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FILED
Amanda Stanford
CLERK, SUPERIOR COURT
09/25/2019 4:23PM
BY: AMONTANA
DEPUTY

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16	PINAL OUNTY,	COUNTY Case No.
16 17 18	PINAL COUNTY,	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING
16 17 18 19	PINAL COUNTY, Plaintiff,	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES,
16 17 18	PINAL COUNTY, Plaintiff, vs. ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA,	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF
16 17 18 19	PINAL COUNTY, Plaintiff, vs. ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; ALLERGAN PLC; AMNEAL	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF (2) NEGLIGENCE (3) NEGLIGENCE PER SE
16 17 18 19 20	PINAL COUNTY, Plaintiff, vs. ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; ALLERGAN PLC; AMNEAL PHARMACEUTICALS INC. f/k/a	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF (2) NEGLIGENCE (3) NEGLIGENCE PER SE (4) UNJUST ENRICHMENT
16 17 18 19 20 21 22	PINAL COUNTY, Plaintiff, vs. ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; ALLERGAN PLC; AMNEAL PHARMACEUTICALS INC. f/k/a AMNEAL PHARMACEUTICALS LLC; CEPHALON, INC.; ENDO HEALTH	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF (2) NEGLIGENCE (3) NEGLIGENCE PER SE (4) UNJUST ENRICHMENT (5) NEGLIGENT FAILURE TO WARN
16 17 18 19 20 21	PINAL COUNTY, Plaintiff, vs. ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; ALLERGAN PLC; AMNEAL PHARMACEUTICALS INC. f/k/a AMNEAL PHARMACEUTICALS LLC; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF (2) NEGLIGENCE (3) NEGLIGENCE PER SE (4) UNJUST ENRICHMENT (5) NEGLIGENT FAILURE TO WARN (6) FRAUDULENT TRANSFER
16 17 18 19 20 21 22	PINAL COUNTY, Plaintiff, vs. ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; ALLERGAN PLC; AMNEAL PHARMACEUTICALS INC. f/k/a AMNEAL PHARMACEUTICALS LLC; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; HOSPIRA, INC.; INDIVIOR, INC.;	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF (2) NEGLIGENCE (3) NEGLIGENCE PER SE (4) UNJUST ENRICHMENT (5) NEGLIGENT FAILURE TO WARN (6) FRAUDULENT TRANSFER (7) CIVIL CONSPIRACY (8) VIOLATION OF CONSUMER
16 17 18 19 20 21 22 23	PINAL COUNTY, Plaintiff, vs. ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; ALLERGAN PLC; AMNEAL PHARMACEUTICALS INC. f/k/a AMNEAL PHARMACEUTICALS LLC; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; HOSPIRA, INC.; INDIVIOR, INC.; JANSSEN PHARMACEUTICA, INC.	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF (2) NEGLIGENCE (3) NEGLIGENCE PER SE (4) UNJUST ENRICHMENT (5) NEGLIGENT FAILURE TO WARN (6) FRAUDULENT TRANSFER (7) CIVIL CONSPIRACY (8) VIOLATION OF CONSUMER FRAUD ACT, A.R.S. § 44-1521
16 17 18 19 20 21 22 23 24 25	PINAL COUNTY, Plaintiff, vs. ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; ALLERGAN PLC; AMNEAL PHARMACEUTICALS INC. f/k/a AMNEAL PHARMACEUTICALS LLC; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; HOSPIRA, INC.; INDIVIOR, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;	Case No. COMPLAINT FOR: (1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF (2) NEGLIGENCE (3) NEGLIGENCE PER SE (4) UNJUST ENRICHMENT (5) NEGLIGENT FAILURE TO WARN (6) FRAUDULENT TRANSFER (7) CIVIL CONSPIRACY (8) VIOLATION OF CONSUMER
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1	MCNEIL-JANSSEN DHADMACEUTICALS INC 1/1/2
2	PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS,
-	INC.; PAR PHARMACEUTICAL, INC.;
3	PAR PHARMACEUTICAL
	COMPANIES; SANDOZ INC.;
4	SPECGX, LLC; TEVA
ا ہ	PHARMACEUTICAL INDUSTRIES,
5	LTD.; TEVA PHARMACEUTICALS
6	USA, INC.; WATSON LABORATORIES, INC.; WATSON
0	PHARMACEUTICALS, INC. n/k/a
7	ACTAVIS, INC.; RICHARD
	SACKLER, an individual; THERESA
8	SACKLER, an individual; KATHE
	SACKLER, an individual; JONATHAN
9	SACKLER, an individual; MORTIMER
10	D.A. SACKLER, an individual; BEVERLY SACKLER, an individual;
10	DAVID SACKLER, an individual;
11	ILENE SACKLER LEFCOURT, an
	individual; JOHN KAPOOR, an
12	individual; MICHAEL BABICH, an
	individual; AMERISOURCEBERGEN
13	DRUG CORP.; CARDINAL HEALTH,
14	INC.; WALMART INC. f/k/a WAL-
14	MART STORES, INC. d/b/a WAL- MART PHARMACY WAREHOUSE #
15	32 and WAL-MART PHARMACY
	WAREHOUSE # 45; SMITH'S FOOD
16	& DRUG CENTERS INC d/b/a FRY'S
17	PHARMACIES AND FRY'S FOOD
17	AND DRUG STORES; BASHAS' INC. d/b/a BASHAS' UNITED DRUG;
18	AMERICAN DRUG STORES INC.
	d/b/a OSCO DRUG, INC.; SAFEWAY
19	INC.; SUN LIFE FÁMILÝ HEALTH
	CENTER; VADEN CORP.;
20	WALGREEN CO.; WALGREEN
$_{21}$	ARIZONA DRUG CO. d/b/a WALGREENS PHARMACIES a/k/a
_1	WALGREENS # 01076, WALGREENS
22	# 06129, WALGREENS # 02963,
	WALGREENS # 04188, WALGREENS
23	# 06333, WALGREENS # 06440,
	WALGREENS # 09264, WALGREENS
24	# 09460, WALGREENS # 09652,
25	WALGREENS # 10505, and WALGREENS # 10998; WALMART,
23	INC. f/k/a WAL-MART STORES, INC.
26	d/b/a WAL-MART PHARMACIES a/k/a
	WAL-MART PHARMACY 10-1218,
27	WAL-MART PHARMACY 10-1381,
20	WAL-MART PHARMACY 10-2778,
28	WAL-MART PHARMACY 10-3751.

and WAL-MART PHARMACY 10-4430; COSTCO WHOLESALE CORPORATION d/b/a COSTCO PHARMACY # 436, COSTCO PHARMACY # 481, and COSTCO PHARMACY # 1028; HARINDER TAKYAR, an individual; and DOES 1 through 1000,

Defendants.

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I. INTRODUCTION

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- Opiates¹ are killing people every day in this country and Arizonans have not 1. been spared. Each of the Defendants in this action engaged in an industry-wide effort to downplay the dangerous and deadly potential effects of the misuse of prescription opioids. The opioid epidemic has hit every community in Arizona hard, including Pinal County ("Pinal County," "Plaintiff," or "the County"). The County brings this Complaint seeking redress for the societal and financial ills it has suffered at the hands of those directly responsible for the crisis—the manufacturers and distributors of prescription opioids.
- 2. This case is about corporate greed. Simply put, each of the Defendants put its desire for profits above the health and well-being of the County's citizens. Pinal and its citizens have paid dearly as a result.
- This case is not about taking away medically necessary opioids from the patients 3. who need them. Plaintiff does not ask the Court to decide whether opioids are clinically appropriate, nor does Plaintiff seek to blame the well-meaning healthcare providers and suppliers who prescribed opioids to their patients in good faith. Instead, Plaintiff only asks that this Court hold the Defendants accountable for the damage they caused to Pinal that Defendants were always in the best position to prevent.

A. The Manufacturer Defendants' Two-Part Scheme to Increase Opioid Sales

4. First, as part of a broader scheme to target all municipalities and counties in the United States where the elements that are most conducive to opioid addiction were prevalent, Defendants ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; ALLERGAN PLC; AMNEAL PHARMACEUTICALS INC. f/k/a AMNEAL PHARMACEUTICALS LLC; CEPHALON, INC; ENDO HEALTH

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The term "opiate" technically refers only to chemicals that occur naturally in the opium plant, including morphine, codeine, thebaine and papaverine. "Opioid," by contrast, refers instead to compounds that have the same effect as opiates but do not occur naturally in the opium plant, such as heroin, oxycodone, hydrocodone, hydromorphone and oxymorphone ("semi-synthetic" opioids) as well as methadone, fentanyl, meperidine and tramadol ("synthetic" opioids).

SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; HOSPIRA, INC.; INDIVIOR,			
INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;			
JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; MALLINCKRODT,			
LLC; MYLAN INSTITUTIONAL INC.; MYLAN PHARMACEUTICALS, INC.; ORTHO-			
MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN			
PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; PAR			
PHARMACEUTICAL COMPANIES; SANDOZ INC.; SPECGX, LLC; TEVA			
PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.;			
INC.; WATSON LABORATORIES, INC.; WATSON PHARMACEUTICALS, INC. n/k/a			
ACTAVIS, INC.; RICHARD SACKLER, an individual; THERESA SACKLER, an			
individual; KATHE SACKLER, an individual; JONATHAN SACKLER, an individual;			
MORTIMER D.A. SACKLER, an individual; BEVERLY SACKLER, an individual; DAVID			
SACKLER, an individual; ILENE SACKLER LEFCOURT, an individual; JOHN KAPOOR,			
an individual; MICHAEL BABICH, an individual ("the Manufacturer Defendants"), targeted			
the State of Arizona, including the citizens of Pinal County. More specifically, the			
Manufacturer Defendants developed and engaged in a sophisticated, manipulative scheme			
designed to increase the number of opioid prescriptions written across the state, including in			
Pinal County. Defendants' scheme was particularly well-suited to Pinal County, because			
Pinal County is home to a multitude of economically and medically vulnerable populations			
that Defendants knew were uniquely predisposed to opioid addiction, including the elderly.			

5. Second, the Manufacturer Defendants succeeded in dramatically increasing the number of opioid prescriptions being written in Pinal County and across the country by (1) affirmatively concealing the truth about the risk of addiction and death associated with long-term use of their products, and (2) pressuring their respective sales forces to deceive (even bribe) local physicians, physician assistants, nurse practitioner and other prescribing clinicians to flood Arizona—and Pinal County—with enough opioid prescriptions for every single person in the County.

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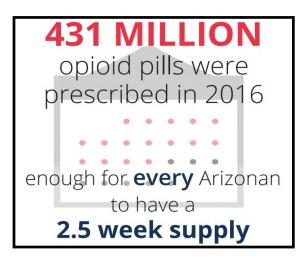
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- B. The Distributor And Pharmacy-Distributor Defendants Turned a Blind Eye to the Manufacturers' Scheme
- 6. Defendants AMERISOURCEBERGEN DRUG CORP and CARDINAL HEALTH, INC. (the "Distributor Defendants"), as well as Defendants WALGREEN ARIZONA DRUG CO.; WALMART INC. f/k/a WAL-MART STORES, INC. d/b/a WAL-MART PHARMACY WAREHOUSE # 32 and WAL-MART PHARMACY WAREHOUSE # 45; SMITH'S FOOD & DRUG CENTERS INC d/b/a FRY'S PHARMACIES and FRY'S FOOD AND DRUG STORES (the "Pharmacy-Distributor Defendants") shipped and dispensed prescription opioids throughout the country, including to addresses in Pinal County. Rather than meet their obligations under Arizona law to report suspicious orders of opioids, the Distributor Defendants and the Pharmacy-Distributor Defendants willfully ignored impossibly large orders being shipped into locations where it was inconceivable that any legitimate medical need could have required the quantities shipped. They failed to report suspicious shipments despite their clear statutory and common law obligations to do so, and in contravention of their own internal policies and procedures. The Distributor Defendants and Pharmacy-Distributor Defendants' breaches of their respective reporting obligations were willful, motivated entirely by the desire to maximize profits, and were committed without consideration of the cost to the County or its citizenry.
 - C. The Pharmacy Defendants Understood But Violated Their Duties
 - 7. Defendants BASHAS' INC. d/b/a BASHAS' UNITED DRUG; SMITH'S

FOOD & DRUG CENTERS INC d/b/a FRY'S PHARMACIES and FRY'S FOOD AND

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DRUG STORES; AMERICAN DRUG STORES INC. d/b/a OSCO DRUG, INC. a/k/a OSCO DRUG #968; SAFEWAY INC; SUN LIFE FAMILY HEALTH CENTER; VADEN CORP; WALGREEN ARIZONA DRUG CO. d/b/a WALGREENS PHARMACIES a/k/a WALGREENS # 01076, WALGREENS # 06129, WALGREENS # 02963, WALGREENS # 04188, WALGREENS # 06333, WALGREENS # 06440, WALGREENS # 09264, WALGREENS # 09460, WALGREENS # 09652, WALGREENS # 10505, and WALGREENS # 10998; and WALMART, INC. f/k/a WAL-MART STORES, INC. d/b/a WAL-MART PHARMACIES a/k/a WAL-MART PHARMACY 10-1218, WAL-MART PHARMACY 10-1381, WAL-MART PHARMACY 10-2778, WAL-MART PHARMACY 10-3751, and WAL-MART PHARMACY 10-4430; and COSTCO WHOLESALE CORPORATION d/b/a COSTCO PHARMACY # 431, COSTCO PHARMACY # 481, and COSTCO PHARMACY # 1028 (collectively, the "Pharmacy Defendants") earned enormous profits by flooding the State of Arizona, including Pinal County, with prescription opioids. They gained unique knowledge of the oversupply of prescription opioids through the extensive data and information they developed and maintained in connection with dispensing opioids to Pinal County patients. Rather than act to stem the flow of opioids into communities like Pinal County, they participated in and profited from the oversupply.

D. The Prescriber Defendant, Harinder Takyar, Manipulated His Patients to Enrich Himself

8. Defendant Harinder Takyar and healthcare providers like him (the "Prescriber Defendants") represent an important component of the Manufacturer Defendants' scheme to flood Arizona, including Pinal, with a wildly inappropriate quantity of opioids. In return for various incentives and to enrich himself, Defendant Takyar facilitated the Manufacturer Defendants' scheme by manipulating his patients about the risks and benefits of opioid therapy for the treatment of chronic pain and prescribing opioids to patients without a legitimate medical need, in violation of prevailing medical standards in, as well as laws and regulations of, Arizona.

E. The Devastating Effects of Defendants' Conduct

9. Each of the Defendants was fully aware that their products placed patients at an unreasonable risk of opioid-related addiction and/or death. Despite this knowledge, the Manufacturer Defendants continue to misrepresent the risks associated with prescription opioids and continue their efforts to influence prescribing clinicians with the goal of increasing sales of prescription opioids to the nation at large, as well as to Pinal County's local, and often its most vulnerable, citizens. Likewise, the Distributor Defendants continue to breach their legal duties to monitor, report, and prevent suspicious shipments of prescription opioids. This conduct precipitated the opioid crisis that has ravaged Plaintiff's communities for years, and will continue to do so for many years, even decades, to come. Defendants' scheme has succeeded—Defendants have made untold billions of dollars from prescription opioids. Meanwhile, the death toll they have caused in the County and elsewhere is unconscionable.

10. Pinal County dedicates substantial portions of its tax revenues to provide and pay for a broad array of services for its population, including healthcare, pharmaceutical care, law enforcement, foster care, public assistance and other necessary services and programs for families and children. However, as a result of the opioid epidemic, the County has been severely hampered in its ability to continue to provide the requisite level of service in each of these categories. This creates a perverse dichotomy. The overburdened service areas require a *greater share* of Pinal County's scarce tax dollars, while at the same time, the crisis itself *decreases* the tax dollars the County can generate. That is because opioid addiction takes productive members of society out of the economy, usually due to death or the inability to work. Simply put, most who become addicted to opioids are no longer able to work, and therefore are no longer able to care for their families, earn a paycheck or spend money in the same way they did before they fell victim to addiction. This predictable downward spiral means the County's tax revenues have suffered. These harms are the direct and proximate result of Defendants' scheme to increase their profits without regard for the end users of

Defendants' drugs, or the municipalities that must bear the brunt of the increased demand for their services brought on by the epidemic.

- 11. In addition to its tax-related damages, Pinal County, a diverse community with great weather and natural beauty, has suffered damage to its reputation at the hands of Defendants. This is due, in large measure, to the opioid epidemic in Pinal County that the Defendants caused, exacerbated and/or failed to abate. Plaintiff has been able to ameliorate this problem, to a degree, only by dedicating substantial tax dollars to measures designed to restore its reputation as a desirable community for both retirees and young families. The financial costs to the County that resulted from the Defendants misdeeds as described in this Complaint, are discussed in detail below, in Section IV.P.
- 12. Things were not always this way in Pinal County. Though Defendants have been manufacturing, marketing, selling and/or prescribing prescription opioids for decades—including brand-name opioids like OxyContin, Percocet and Duragesic, as well as the generic formulations of these drugs, oxycodone, hydrocodone and fentanyl—only since the late 1990s have Defendants' powerful narcotic painkillers been used to treat more than just short-term, acute or cancer-related pain. Indeed, for the vast majority of the twentieth century, Defendants' drugs were considered too addictive and debilitating for patients suffering from long-term (chronic) pain due to non-cancer conditions like arthritis, fibromyalgia and migraines.²
- 13. In the late 1990s, however, and continuing today, Defendants began a sophisticated marketing and distribution scheme premised on deception to persuade prescribing clinicians and patients that opioids can and should be used to treat chronic pain. Defendants spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids for treating chronic pain. As to the risks, Defendants falsely and misleadingly: (1) downplayed the serious risk of opioid addiction;³ (2) promoted the concept of

² In this Complaint, "chronic pain" refers to non-cancer pain lasting three months or longer.

³ Addiction is classified as a spectrum of "substance use disorders" that range from misuse

- 14. Indeed, at all times relevant to this action, these Defendants knew that their longstanding and ongoing misrepresentations of the risks and benefits of opioids were not supported by, or were directly contrary to, the scientific evidence. Moreover, regulators and the medical community at large have recognized the serious risks posed by opioid pain medications. Indeed, according to recently established and widely accepted clinical guidelines for opioid therapy, "[t]he science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits."
- 15. Opioid manufacturers, including Defendant Endo Pharmaceuticals, Inc., have also entered into agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet, even now, Defendants continue to misrepresent the risks and benefits of long-term opioid use in Arizona, including in the County, and continue to fail to correct their past misrepresentations.

and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on this spectrum. In this Complaint, "addiction" refers to the entire range of substance abuse disorders. [American Society of Addiction Medicine Public Policy Statements: https://www.asam.org/docs/default-source/public-policy-statements/1-terminology-spectrum-sud-7-13.pdf?sfvrsn=d93c69c2_2.

⁴ Thomas R. Frieden et al., *Reducing the Risks of Relief*—*The Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

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16. Specifically, Defendants concealed what their own internal documents and communications show they already knew, and had known for decades: not only were Defendants' opioids inappropriate and, in fact, life-threatening for non-cancer patients with chronic pain, but further, none of Defendants' representations about the manageability or prevention of opioid addiction was true. As set forth in detail below, for decades the Manufacturer and Distributor Defendants have made and continue to make a series of inaccurate claims about the risks and benefits associated with their opioids, essentially bribing Key Opinion Leader ("KOL") group to substantiate the veracity of Defendants' false statements. In creating the illusion that prescription opioids were a low-risk treatment option for chronic pain relative to nonsteroidal anti-inflammatory drugs ("NSAIDs") and other nonopioid pharmacologic approaches, Defendants successfully targeted vulnerable patient populations, like the elderly and opioid naïve patients. Defendants further tainted the sources that prescribing clinicians and patients in Pinal County relied upon for guidance, including treatment guidelines, continuing medical education programs, medical conferences and seminars, and scientific articles. As a result, Defendants successfully transformed the way doctors and other clinicians in Pinal County treat chronic pain, opening the floodgates for opioid prescribing and use and creating an illicit market for Defendants' opioids. explosion in opioid prescriptions and use has padded Defendants' profit margins at the expense of chronic pain patients. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in Arizona and, in particular, Pinal County. Arizona faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it "is injurious to health" and interferes "with the comfortable enjoyment of life and property" (A.R.S. § 13-2917(A)) and because it affects "entire communit[ies]" and "neighborhood[s]" and "any considerable number of persons" (*Id.*) The effects of Defendants' deceptive marketing scheme are catastrophic and are only getting worse. These effects are devastating in Arizona. More than two Arizonans die each day from an opioid overdose. There has been a 74% increase in deaths among Arizona citizens since 2012. Indeed, in

 February 2016 regulators acknowledged that "[t]hings are getting worse, not better, with the epidemic of opioid misuse, abuse and dependence."

- 17. There is little doubt that Defendants' deceptive marketing and distribution scheme has precipitated this public health crisis in Arizona, including in Pinal County, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.
- 18. Defendants' deceptive marketing and distribution scheme have had further foreseeable impacts on Pinal County. As a result of Defendants' conduct, the County must devote resources to mitigate the incidence of opioid-related crimes, to feed their addiction. For example, tax dollars are required to maintain public safety of places where opioid addicts attempt to congregate and effectively exacerbate the opioid crisis throughout the County, including in the County's jails, as well as in the parks, schools, and other public lands in the unincorporated areas of Pinal County that the County's law enforcement officials are responsible for patrolling to prevent opioid diversion and to abate the opioid epidemic in the County. Tax dollars are required to both provide increased security and health services for the County's jail population as well as fight the infectious diseases that are often spread in connection with opioid addiction and abuse, including Hepatitis B and C, HIV, sexually transmitted infections and methicillin-resistant Staphylococcus aureus ("MRSA").
- 19. Defendants' willful and wrongful conduct has further impacted Pinal County by creating a public nuisance in the County, which Defendants foresaw yet deliberately ignored. Defendants were aware at all relevant times when they deceptively marketed their products as non-addictive that such addiction would be highly difficult to overcome.
- 20. The role of Defendants' deceptive marketing and distribution scheme in causing this public health crisis has become well-recognized in recent years. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of regulators, Dr.

Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem." In the years since her comments were initially published, Dr. Volkow's message has become the dominant view of the top experts and influencers in the medical community, who are finally realizing just how dangerous Defendants' opioids are, and how devastating the economic and social costs of Defendants' intentional deception has been.⁶

- 21. Absent the Manufacturer Defendants' deceptive marketing scheme, the Distributor and Pharmacy Defendants' improper distribution, and the Prescriber Defendants' improper prescribing, the opioid use, misuse, abuse, and addiction in Pinal County would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.
- 22. By falsely downplaying the risks and grossly exaggerating the benefits of long-term opioid use through their deceptive marketing claims despite their knowledge of the falsity of those claims, and by improperly distributing and prescribing prescription opioids as set forth herein, Defendants have not only engaged in false advertising and unfair competition, they have also created or assisted in the creation of a public nuisance. Although this Complaint focuses on Defendants' misconduct during the past six years and only references their earlier misconduct, every act of malfeasance committed by each Defendant since the late 1990s as part of its deceptive marketing and distribution scheme subjects that Defendant to liability for public nuisance because there is no statute of limitations for a public nuisance claim. See A.R.S. § 13-2917(A).
- 23. Accordingly, Defendants' conduct, both individually and collectively, has violated and continues to violate Arizona's Public Nuisance Law, A.R.S. § 13-2917. Pinal

N. Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, National Institute on Drug Abuse, (May 14, 2014), available at: https://www.drugabuse.gov/about-nida/legislative-activities/testimony-tocongress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

⁶ E. O'Brien, *Here's What it Would Cost to Fix the Opioid Crisis, According to 5 Experts*, Time Money (Nov. 27, 2017), http://time.com/money/5032445/cost-fix-opioid-crisis/.

County does not ask this Court to weigh the risks and benefits of long-term opioid use. Instead, Pinal County seeks an order requiring Defendants to cease their unlawful promotion, distribution, and prescribing of opioids, to correct their misrepresentations, and to abate the public nuisance they have created in the County. To redress and punish Defendants' previous and current violations of law that caused and continue to cause harm to Pinal County and its citizens, Pinal County seeks a judgment requiring Defendants to pay civil damages, and any fees, costs and penalties permitted under law, in an amount to be determined at trial.

24. By this action, Pinal County further seeks to recoup tax dollars spent already for the consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its impact on Pinal County, and to abate the opioid nuisance so Pinal County will not be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants' wrongful conduct.

II. PARTIES

A. Plaintiff

- 25. Pinal County, Arizona, by and through its attorneys hereto, hereby brings this action on behalf of the people of Pinal County to protect the public from false and misleading advertising, unlawful, unfair, and fraudulent business practices, and a public nuisance.
- 26. Pinal County was formed out of portions of Maricopa and Pima Counties on February 1, 1875, during the Eighth Legislature. According to recent U.S. Census Bureau estimates, Pinal County is the third-most populous county in Arizona. The County comprises over 5,300 square miles of diversely scenic beauty, including the low desert valleys and irrigated agriculture of Pinal's western region as well as the iconic mountain ranges and copper mines in the eastern portions of the County. Water enthusiasts can visit several lakes in the northeast of the County, enjoying fishing, swimming and water skiing year round. The County also offers spectacular panoramic views and historic outdoor sites, such as the Old West Highway 60, Picacho Peak, Casa Grande Ruins, Boyce Thompson Southwestern Arboretum and Biosphere II, as well as the Picacho Reservoir, which offers fine fishing,

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hunting and bird watching for many rare species.⁷ As such, the County's economy relies heavily on tourism.

B. Manufacturer Defendants

1. Actavis/Allergan

27. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in June 2015. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is registered to do business in the State of Arizona as a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis PLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these Defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to in this Complaint as "Actavis.")

28. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Arizona. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

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 10 See Pinal County—Activities & Attractions, available at http://www.pinalcountyaz.gov/Visitors/Pages/Eloy.aspx.

2. Cephalon

- 29. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. It is registered to do business in Arizona.
- 30. Cephalon manufactures, promotes, sells, and distributes fentanyl-based opioids such as Actiq and Fentora in the United States. Both Actiq and Fentora are over 100-times more powerful than morphine. Thus, Actiq is approved only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain." Similarly, Fentora is approved only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Neither Actiq nor Fentora are appropriate treatments for chronic pain.

3. Teva

- 31. Teva Ltd., Teva USA, and Cephalon work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs prescribers to contact Teva USA to report adverse events.
- 32. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012—the year immediately following the Cephalon

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acquisition—attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including—*inter alia*—sales of Fentora. Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva has engaged in consensual commercial dealings with Pinal County's citizens, and has purposefully availed itself of the advantages of conducting business with and within Pinal County. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon" for the remainder of this Complaint.

4. Endo/Par

33. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania (collectively, Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. are referred to as "Endo"). Endo develops, markets, and sells prescription drugs, including the brand-name opioids Opana IR/Opana ER, Endodan, Endocet, Percodan, Percocet, Hycodan and Zydone. Endo also manufactures and sells generic opioid drugs—i.e., oxymorphone, oxycodone, hydrocodone, morphine, codeine —in the U.S. and Arizona, by itself and through its subsidiaries, Qualitest Pharmaceuticals, Inc and Par Pharmaceuticals, Inc. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER, for instance, yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012.

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34. Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par") are New York corporations with their principal places of business in New York. Par was acquired by Endo in 2015. Par is the fifth largest manufacturer of generic pharmaceuticals in the world, including oxycodone, oxymorphone, and hydrocodone. At all times relevant, Par manufactured and marketed prescription opioids throughout the United States, including in Arizona and Pinal County specifically. Par has engaged in consensual commercial dealings with Pinal County's citizens and has purposefully availed itself of the advantages of conducting business with and within Pinal County. On information and belief, in 2013, Par pleaded guilty to misbranding its drugs. For the remainder of this Complaint, Endo and Par are referred to collectively as "Endo."

5. Janssen

- 35. Janssen Pharmaceuticals, Inc. (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. These entities, which are collectively referred to herein as "Janssen," acted in concert with one another—as agents and/or principals of one another—in connection with the conduct described herein. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with regulators regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. The Janssen and J&J parties are collectively referred to as "Janssen."
- 36. Janssen manufactures, promotes, sells, and distributes opioids in the U.S. and Arizona, including the fentanyl-based opioid, Duragesic (which is 100-times more powerful than morphine). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta IR and Nucynta ER, which also generated substantial sales revenue for the company, accounting for \$172 million in sales in 2014 alone.

6. Johnson & Johnson

37. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

- 38. In addition, J&J made payments to front groups, discussed herein, who perpetuated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids.⁸
 - 7. The Purdue Individual Defendants: Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler
- 39. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and the Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").
- 40. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, ⁹ and Targiniq ER in the

⁸ U.S. Senate Homeland Security & Governmental Affairs Committee ("HSGAC"), Ranking Member's Office, Minority Staff Report No. 2, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, p. 4, n. 23 (2018) ("Payments from Janssen include payments from Johnson & Johnson Health Care Systems, Inc."), https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%

20Third%20Party%20Advocacy%20Groups.pdf.

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U.S. and Arizona. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

- 41. The Sackler family—Defendants Richard Sackler, Theresa Sackler, Kathe Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Beverly Sackler, David Sackler, and Ilene Sackler Lefcourt (collectively, "the Sacklers")—own Purdue, and they always held a majority of the seats on its Board. Because they controlled their own privately held drug company, the Sacklers had the power to decide how addictive narcotics were sold.
- 42. Beverly Sackler, Jonathan Sackler, and Kathe Sackler reside in Connecticut. David Sackler, Ilene Sackler Lefcourt, and Mortimer Sackler reside in New York. Richard Sackler, resides in Florida, and Theresa Sackler resides in the United Kingdom.

8. Mallinckrodt/SpecGx

- 43. Defendant Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt PLC was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien PLC, which was fully transferred to Mallinckrodt in June of that year. Mallinckrodt began as a U.S.-based company, with the founding of Mallinckrodt & Co. in 1867; Tyco International Ltd. acquired the company in 2000. In 2008, Tyco Healthcare Group separated from Tyco International and renamed itself Covidien.
- 44. Defendant Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware, headquartered in St. Louis, Missouri and licensed to do business in Arizona. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC.
- 45. Defendant SpecGX LLC ("SpecGX") is a limited liability company formed in Delaware and headquartered in St. Louis, Missouri. SpecGX is a wholly owned subsidiary of Mallinckrodt plc. According to a filing with the Secretary of State, Marvin Haselhorst is the designated member or manager of SpecGX, with a business address located in Webster

Groves, Missouri. SpecGX is registered to do business in the State of Arizona and to manufacture its products at the address of 3600 North Second Street, Saint Louis, Missouri 63147.

- 46. Together, Mallinckrodt plc, Mallinckrodt, LLC and SpecGX LLC (collectively, "Mallinckrodt") manufacture, market, and sell drugs in the United States. As of 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the largest manufacturers of oxycodone in the U.S.
- 47. Mallinckrodt currently manufactures and markets several branded opioids, including Exalgo, Roxicodone and Methadose. In addition, Mallinckrodt previously developed, promoted, and sold the following branded opioid products: Magnacet, TussiCaps, and Xartemis XR.
- 48. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids, including hydromorphone, oxycodone, methadone and fentanyl. Mallinckrodt estimated that in 2015 it received approximately 25% of one regulator's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on health data for the same period, that its generics claimed an approximately 23% market share of opioid and oral solid dose medications.
- 49. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials; (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York; and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups, including in Pinal County.

9. Sandoz

50. A subsidiary of Novartis International AG, Defendant Novartis Pharmaceuticals Corporation f/k/a Sandoz, Inc. ("Sandoz") is headquartered in Princeton, New Jersey and develops, manufactures, markets and distributes generic pharmaceutical products, including fentanyl. At all times relevant, Sandoz manufactured and marketed prescription opioids

throughout the United States, including in Arizona and Pinal County specifically. On information and belief, Sandoz is a top manufacturer of fentanyl to Pinal County.

10. Mylan

- 51. Defendant Mylan Institutional Inc. ("Mylan Institutional") is an Illinois corporation headquartered in Rockford, Illinois. Mylan manufactures and markets pharmaceutical products. Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is based in Morgantown, West Virginia, and is also a major manufacturer and marketer of opioids in Pinal County. Both Mylan Institutional and Mylan Pharmaceuticals are subsidiaries of Defendant Mylan N.V., the second-largest generic and specialty pharmaceuticals company in the world, registered in the Netherlands with principal executive offices in Hatfield, Hertfordshire, UK and a global center in Canonsburg, Pennsylvania. (Mylan Institutional, Mylan Pharmaceuticals, and Mylan N.V. shall collectively be referred to as "Mylan"). At all times relevant, Mylan manufactured and marketed prescription opioids throughout the United States, including in Arizona and Pinal County specifically. On information and belief, Mylan is a top manufacturer of fentanyl, oxycodone, morphine and codeine in Pinal County.
- 52. In 2000, Mylan agreed to pay \$100M to resolve allegations that it conspired to deny its competitors certain necessary ingredients to manufacture several widely-prescribed medications, including treatments for opioid use disorder and opioid addiction. As alleged in petitions filed by thirty-two State Attorneys General and the District of Columbia, Mylan's conduct caused substantial price increases in, and improperly limited the supply of, these treatments.

11. Hospira, Inc.

53. Defendant Hospira, Inc. ("Hospira"), a Delaware corporation, with its principle place of business in Lake Forest, Illinois and is the former hospital-products division of Abbott Laboratories. Hospira was the world's largest producer of generic injectable pharmaceuticals before being acquired by Pfizer in September 2015. Since then, Hospira has been cited by regulatory agencies for both failing to operate its manufacturing facilities in compliance with basic health and safety guidelines intended to prevent microbiological

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contamination of Hospira's products—including opioids—and for failing to investigate known defects in its products.

54. At all times relevant to this action, Hospira manufactured and marketed opioids across the county and in Arizona and Pinal County specifically. On information and belief, Hospira is a top manufacturer of fentanyl, morphine, hydromorphone, meperidine and buprenorphine in Pinal County.

12. Amneal Pharmaceuticals

55. Defendant Amneal Pharmaceuticals Inc, f/k/a Amneal Pharmaceuticals LLC ("Amneal") is a Delaware corporation with its principal place of business in Bridgewater, New Jersey and is the fifth largest United States generics company. At all times relevant, Amneal manufactured, marketed and/or distributed prescription opioids throughout the United States, including in Arizona and Pinal County specifically. On information and belief, Amneal is a top manufacturer of oxycodone and hydrocodone in Pinal County. Amneal is currently the subject of an investigation regarding allegations that Amneal provided misleading information to the investing public.

13. The Insys Individual Defendants: John Kapoor and Michael Babich

- 56. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures, markets, sells and distributes nationwide several types of opioids, including Subsys—a fentanyl sublingual spray and semi-synthetic opioid antagonist—as well as Syndros, a cannabinoid medicine used in adults to treat common side-effects of opioid use, particularly for patients whose nausea and vomiting have not improved with usual anti-nausea and vomiting medicines. Subsys and Syndros hit the market in 2012 and 2016, respectively.
- 57. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain." The indication also specifies that "Subsys is intended to

¹⁰ The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg

be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.

- 58. Insys's revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of \$331 million. Of that total, \$329.5 million was derived from sales of Subsys. The majority of Insys's sales of Subsys are through wholesalers, including Defendants AmerisourceBergen and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17% and 14% of Insys's total gross sales of Subsys.
- 59. On Friday, June 7, 2019, the pharmaceutical arm of Insys Therapeutics Inc. formally pleaded guilty to federal charges connected to allegations the company bribed doctors to prescribe a powerful opioid to patients who didn't need it, part of a \$225 million deal entered into with the federal government in United States District Court for the District of Massachusetts.¹¹
- 60. John Kapoor is the founder and majority owner of Insys. In October of 2017, Defendant Kapoor was arrested in Arizona and charged with various violations of fraud and abuse laws as well as conspiracy, for his alleged participation in a nationwide scheme to bribe healthcare providers in various states, including Arizona, to prescribe Subsys. On May 2, 2019, he was found guilty of these changers in connection with running a nation-wide bribery scheme.¹² He is a citizen of Phoenix, Arizona and a current member of the Board of Directors

of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

https://www.law360.com/articles/1166925/insys-pleads-guilty-to-fraud-in-opioid-bribescheme.

Gabrielle Emanuel, *Opioid Executive John Kapoor Found Guilty in Landmark Bribery Case* (May 2, 2019) https://www.npr.org/2019/05/02/711346081/opioid-executive-john-kapoor-found-guilty-in-landmark-bribery-case.

of Insys.

61. Michael Babich is the former CEO and President of Insys. In 2017, he was also arrested in Arizona on charges of various violations of fraud and abuse laws as well as conspiracy, in connection running a nationwide bribery scheme intended to bribe or deceive healthcare providers in various states, including Arizona, to prescribe Subsys. In January of 2019, Defendant Babich pleaded to these charges.¹³ He is a citizen of Scottsdale, Arizona.

C. Distributor Defendants

1. AmerisourceBergen

62. Defendant Distributor AmerisourceBergen ("AmerisourceBergen") is a publicly traded company headquartered in Pennsylvania and incorporated under the laws of Delaware. AmerisourceBergen is in the chain of distribution of prescription opioids. At all relevant times, AmerisourceBergen was in the business of distributing substantial amounts of prescription opioids to providers and retailers. AmerisourceBergen has engaged in consensual commercial dealings with Pinal County and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Pinal County.

2. Cardinal Health

- 63. Defendant Distributor Cardinal Health, Inc. (hereinafter "Cardinal Health") is a publicly traded company headquartered in the State of Ohio and incorporated under the laws of Ohio. Cardinal Health is in the chain of distribution of prescription opioids. At all relevant times, Distributor Cardinal Health was in the business of distributing substantial amounts of prescription opioids to providers and retailers. Cardinal Health has engaged in consensual commercial dealings with Pinal County and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Pinal County.
- 64. Defendants AmerisourceBergen and Cardinal Health are collectively referred to as the "Distributor Defendants." Manufacturers of opioids have transferred prescription

¹³ Jonathan Saltzman, *Former CEO says Insys founder pushed for higher doses of opioid*, Boston Globe (Feb. 12, 2019), https://www2.bostonglobe.com/business/2019/02/12/former-ceo-says-insys-founder-pushed-for-higher-doses-

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opioids to the Distributor Defendants for years. The Distributor Defendants dominate 85 to 90 percent of all revenues from drug distribution in the United States, estimated to be at \$378.4 billion in 2015. The Distributor Defendants supplied opioids to hospitals, pharmacies, doctors and other healthcare providers, which then dispensed the drugs to patients in Arizona, including in Pinal County. The Distributor Defendants have had substantial contacts and business relationships with the people of Pinal County. The Distributor Defendants have purposefully availed themselves of business opportunities within Pinal County.

3. Walmart

- 65. Defendant Walmart Inc. f/k/a Wal-Mart Stores, Inc. ("Walmart") is a Delaware corporation with its principle place of business in Arkansas.
- 66. At all times relevant, Walmart distributed prescription opioids throughout the United States, including in Arizona and Pinal County specifically. On information and belief, these opioids were distributed to Pinal County by at least two Walmart entities: Wal-Mart Pharm Warehouse # 32 (located at 2252 North 8th Street in Rogers, Arkansas) and Wal-Mart Pharm Warehouse #45 (located at 2250 North 8th Street, Suite 102-A in Rogers, Arkansas) to five buyers located in Pinal County: Wal-Mart Pharmacy 10-1218, based in Casa Grande, Arizona; Wal-Mart Pharmacy 10-1381, based in Apache Junction, Arizona; Wal-Mart Pharmacy 10-2778, based in Coolidge, Arizona; Wal-Mart Pharmacy 10-3751, based in San Tan Valley, Arizona; and Wal-Mart Pharmacy 10-4430, based in Maricopa, Arizona. On information and belief, Walmart is a top distributor of opioids in Pinal County. Walmart has engaged in consensual commercial dealings in Pinal County, and has purposefully availed itself of the advantages of conducting business with and within Pinal County. Walmart is in the chain of distribution of prescription opioids. As reported by the Washington Post, there were 100,000 prescription opioid deaths between 2006 and 2012, during which time twothirds of the 76 billion opioid pain pills to flood the market were distributed by Walmart and

opioid/aZhLcDEnayOO3dzPlFn9gN/story.html.

just a handful of other companies.¹⁴ In 2016, Walmart expanded its long-term prescription drug distribution agreement.¹⁵ Walmart's total revenue exceeded \$500 billion in 2018.

67. In 2017, Walmart acknowledged the need for a "solution to the [opioid] epidemic" and noted the epidemic has "devastated so many families and communities across America." However, on information and belief, Walmart has also paid settlements to resolve allegations of recordkeeping violations at pharmacies in various states, including Texas, and has committed and continues to commit serious and flagrant violations regarding—*inter alia*—its recordkeeping and other obligations under Arizona law in connection with its distribution of opioids to Pinal County.

4. Smith's Food & Drug Centers d/b/a Fry's Food & Drugs

68. Defendant Smith's Food & Drug Centers, Inc. d/b/a Fry's Food & Drug and Fry's Food Stores (collectively, "Fry's") is an Ohio corporation with its principle place of business in Salt Lake City, Utah. On information and belief, Defendant Fry's is a top distributor of opioids to Pinal County patients that has distributed and continues to distribute opioids to several chain pharmacies that are both owned and operated by Defendant Fry's as well as frequently visited by Pinal County patients seeking to fill their opioids prescriptions. Defendant Fry's pharmacies are—on information and belief—top dispensers of opioids in the

¹⁴ See Scott Higham, 76 billion opioid pills: Newly released data unmasks the epidemic, The Washington Post (Jul. 16, 2019), available at https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9 story.html; see also Walmart, CVS, Walgreens Opioid Crisis Lawsuit, VOX

⁽July 23, 2019), available at https://www.vox.com/the-goods/2019/7/23/20707179/walmart-cvs-walgreens-opioid-crisis-lawsuit-trial.

15 See Chain Drug Review, Extended Agreement Adds Sourcing of Generic Drugs (May 16,

^{2016),} available at https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=13&cad=rja&uact=8

[&]amp;ved=2ahUKEwjB49eAsobkAhWCsJ4KHTTkBHcQFjAMegQIABAB&url=https%3A%2F%2Fwww.chaindrugreview.com%2Fmckesson-walmart-add-generics-to-drug-distribution-pact%2F&usg=AOvVaw2MokrhSkXhg2hRFgY-VEhH.

¹⁶ Press Release, Walmart, Walmart Supports the State of Emergency Declaration on Opioids (Oct. 26, 2017), https://news.walmart.com/2017/10/26/walmart-supports-state-of-emergency-declaration-on-opioids.

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County, including: Fry's Pharmacy # 48, located at 1385 East Florence Boulevard in Casa Grande, Arizona; Fry's Pharmacy # 672, located at 20797 North John Wayne Parkway in Maricopa, Arizona; Fry's Food Stores of AZ # 669, located at 2858 North Pinal Avenue in Casa Grande, Arizona; Fry's Food Stores # 84, located at 542 East Hunt Highway in San Tan Valley, Arizona; and Fry's Pharmacy # 665, located at 185 West Apache Trail in Apache Junction, Arizona 85120. In addition, Defendant Fry's operates several chain pharmacies located just a few miles outside the County, which have been and continue to be frequently visited by many Pinal County patients seeking to fill their opioid prescriptions. information and belief, Defendant Fry's is a top distributor of opioids to Pinal County patients that has committed and continues to commit serious and flagrant violations regarding—inter alia—its recordkeeping and other obligations under Arizona law in connection with its distribution of opioids to its chain pharmacies, which ultimately dispensed the drugs to Pinal County patients.

5. Walgreens

Defendant Walgreen Arizona Drug Co. ("Walgreens") is a domestic Arizona 69. corporation with its principle place of business located at 8825 N 23rd Avenue, Suite 100 in Phoenix, Arizona. On information and belief, Defendant Walgreens is both a top distributor of opioids in Pinal County and operates chain pharmacies that are top dispensers of opioids in the County, including: Walgreens # 01076, located at 333 E Hunt Highway in Queen Creek, Arizona; Walgreens # 02963, located at 11545 Apache Trail in Apache Junction, Arizona; Walgreens #04188, located at 55 W. Apache Trail in Apache Junction, Arizona; Walgreens # 04344, located at 1514 East Florence Boulevard in Casa Grande, Arizona; Walgreens # 06129, located at 2021 North Pinal Avenue in Casa Grande, Arizona; Walgreens # 06333, located at 2440 South Ironwood Drive in Apache Junction, Arizona; Walgreens # 06440, located at 6951 South Kings Ranch Road in Gold Canyon, Arizona; Walgreens # 09264, located at 21274 North John Wayne Parkway in Maricopa, Arizona; Walgreens # 09460, located at 40663 North Gantzel Road in San Tan Valley, Arizona; Walgreens # 09652, located at 1575 North Arizona Boulevard in Coolidge, Arizona; Walgreens # 10505, located at 2785 North Pinal

Avenue in Casa Grande, Arizona; and Walgreens # 10998, located at 2483 East Florence Boulevard in Casa Grande, Arizona.

70. In 2016, Walgreens issued a press release captioned "Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths." However, on information and belief, Walgreens, the second-largest pharmacy store chain in the United States, has committed, continues to commit and has been penalized for serious and flagrant violations regarding its recordkeeping and other obligations under Arizona law in connection with its distribution of opioids to Pinal County. Defendants AmerisourceBergen, Cardinal Health, Walmart, Fry's, and Walgreens are referred to collectively in this Complaint as "Distributor Defendants."

D. Pharmacy Defendants

1. Bashas' Inc.

71. Defendant Bashas' Inc. d/b/a Bashas' United Drug ("Bashas") is an Arizona domestic corporation with its principle place of business in Phoenix, Arizona. Bashas operates several retail pharmacies in Pinal County, including Basha's United Drug # 82, located at 5311 S. Superstition Mountain in Gold Canyon, Arizona, and Basha's United Drug # 109, located at 21044 N John Wayne Pkwy in Maricopa, Arizona. In addition, Defendant Bashas operates several chain pharmacies located outside but along the borders of the County which have been and continue to be frequently visited by many Pinal County patients seeking to have their opioid prescriptions filled, such as Basha's United Drug # 22, located in Maricopa County at 10715 E Apache Trail in Apache Junction, Arizona. On information and belief, Bashas' pharmacies are top dispensers of opioids to Pinal County patients and have committed and continue to commit serious and flagrant violations regarding—*inter alia*—their recordkeeping and other obligations under Arizona law in connection with dispensing opioids

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¹⁷ Press Release, Walgreens, Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths (Feb. 9, 2016), http://news.walgreens.com/press-releases/general-news/walgreens-leads-fight-against-prescription-drug-abuse-with-new-programs-to-help-curb-misuse-of-medications-and-the-rise-in-overdose-deaths.htm.

to these patients. Bashas and its pharmacies have engaged in consensual commercial dealings in Pinal County, and have purposefully availed themselves of the advantages of conducting business with and within Pinal County.

2. Osco Drug Inc.

72. Defendant American Drug Stores, Inc. d/b/a Osco Drug Inc. ("Osco Drug") is an Illinois corporation with its principal place of business in Boise, Idaho. Defendant Osco Drug operates chain pharmacies throughout the State of Arizona and in Pinal County, including Osco Drug Store # 968, which is a chain pharmacy located in Pinal County at 1116 E Florence Blvd in Casa Grande, Arizona. On information and belief, Osco Drug and its pharmacies are top dispensers of opioids in Pinal County that have committed and continue to commit serious and flagrant violations regarding—*inter alia*—their recordkeeping and other obligations under Arizona law in connection with dispensing opioids to Pinal County patients. Osco Drug and its pharmacies have engaged in consensual commercial dealings in Pinal County, and have purposefully availed themselves of the advantages of conducting business with and within Pinal County.

3. Safeway Inc.

73. Defendant Safeway Inc. ("Safeway") is a Delaware corporation with its principle place of business in Pleasanton, California. Safeway operates several chain pharmacies in Pinal County, including: Safeway Pharmacy # 0253, located at 3185 W. Apache Trail in Apache Junction, Arizona; Safeway Pharmacy # 1706, located at 1637 Trekell Rd in Casa Grande, Arizona; Safeway Pharmacy # 1732, located at 1449 N. Arizona Avenue in Coolidge, Arizona; and Safeway Pharmacy # 2835, located at 3325 North Hunt Highway in Florence, Arizona. On information and belief, Safeway and its pharmacies are top dispensers of opioids in Pinal County that have committed and continue to commit serious and flagrant violations regarding—*inter alia*—their recordkeeping and other obligations under Arizona law in connection with dispensing opioids to Pinal County patients. Safeway and its pharmacies have engaged in consensual commercial dealings in Pinal County, and have purposefully availed themselves of the advantages of conducting business with and within Pinal County.

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4. Smith's Food & Drug Centers d/b/a Fry's Food & Drugs

74. Defendant Smith's Food & Drug Centers, Inc. d/b/a Frys Food & Drug and Fry's Food Stores (collectively, "Fry's") is an Ohio corporation with its principle place of business in Salt Lake City, Utah. Defendant Fry's operates several chain pharmacies located in Pinal County, including: Fry's Pharmacy #48, located at 1385 East Florence Boulevard. in Casa Grande, Arizona; Fry's Pharmacy #672, located at 20797 North John Wayne Parkway in Maricopa, Arizona; Fry's Food Stores of AZ # 669, located at 2858 North Pinal Avenue in Casa Grande, Arizona; and Fry's Food Stores # 84, located at 542 East Hunt Highway in San Tan Valley, Arizona; and Fry's Pharmacy # 665, located at 185 West Apache Trail in Apache Junction, Arizona 85120. In addition, Defendant Fry's operates several chain pharmacies located outside but along the borders of the County which have been and continue to be frequently visited by many Pinal County patients seeking to fill their opioid prescriptions. On information and belief, Fry's and its pharmacies are top dispensers of opioids to Pinal County patients and have committed and continue to commit serious and flagrant violations regarding—inter alia—their recordkeeping and other obligations under Arizona law in connection with dispensing opioids to these patients. Fry's and its pharmacies have engaged in consensual commercial dealings in Pinal County, and have purposefully availed themselves of the advantages of conducting business with and within Pinal County.

5. Sun Life Family Health Center

75. Defendant Sun Life Family Health Center ("SLFHC") is an Arizona corporation with its principle place of business in Casa Grande, Arizona. Defendant SLFHC operates retail pharmacies in the County, including SLFHC's retail pharmacy located at 865 N. Arizola Rd. in Casa Grande, Arizona; SLFHC's retail pharmacy located in SLFHC's Eloy Clinic at 205 N. Stuart Boulevard in Eloy, Arizona; and SLFHC's retail pharmacy located at 23 McNab Parkway in San Manuel, Arizona. On information and belief, SLFHC and its pharmacies are top dispensers of opioids in Pinal County that have committed and continue to commit serious and flagrant violations regarding—*inter alia*—their recordkeeping and other obligations under Arizona law in connection with dispensing opioids to Pinal County patients. SLFHC and its

pharmacies have engaged in consensual commercial dealings in Pinal County, and have purposefully availed themselves of the advantages of conducting business with and within Pinal County.

6. Vaden

76. Defendant Vaden Corp. ("Vaden") is a California corporation with its principle place of business in Simi Valley, California. Defendant Vaden operates retail pharmacies in the County, including Kearny HealthMart Pharmacy # 25, located at 338 Alden Road P.O. Box 1150 in Kearny, Arizona. On information and belief, Vaden and its pharmacies are top dispensers of opioids in Pinal County that have committed and continue to commit serious and flagrant violations regarding—*inter alia*—their recordkeeping and other obligations under Arizona law in connection with dispensing opioids to Pinal County patients. Vaden and its pharmacies have engaged in consensual commercial dealings in Pinal County, and have purposefully availed themselves of the advantages of conducting business with and within Pinal County.

7. Walgreens

77. Defendant Walgreen Arizona Drug Co. ("Walgreens") is a domestic Arizona corporation with its principle place of business located at 8825 N 23rd Avenue, Suite 100 in Phoenix, Arizona. Defendant Walgreens operates chain pharmacies in the County, including: Walgreens # 01076, located at 333 East Hunt Highway in Queen Creek, Arizona; Walgreens # 02963, located at 11545 Apache Trail in Apache Junction, Arizona; Walgreens # 04188, located at 55 West Apache Trail in Apache Junction, Arizona; Walgreens # 04344, located at 1514 East Florence Blvd in Casa Grande, Arizona; Walgreens # 06129, located at 2021 North Pinal Avenue in Casa Grande, Arizona; Walgreens # 06333, located at 2440 South Ironwood Drive in Apache Junction, Arizona; Walgreens # 06440, located at 6951 South Kings Ranch Road in Gold Canyon, Arizona; Walgreens # 09264, located at 21274 North John Wayne Parkway in Maricopa, Arizona; Walgreens # 09460, located at 40663 North Gantzel Road in San Tan Valley, Arizona; Walgreens # 09652, located at 1575 North Arizona Boulevard in Coolidge, Arizona; Walgreens # 10505, located at 2785 North Pinal Avenue in Casa Grande,

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Arizona; and Walgreens # 10998, located at 2483 East Florence Boulevard in Casa Grande, Arizona. On information and belief, Walgreens and its pharmacies are top dispensers of opioids in Pinal County that have committed and continue to commit serious and flagrant violations regarding—*inter alia*—their recordkeeping and other obligations under Arizona law in connection with dispensing opioids to Pinal County patients. Walgreens and its pharmacies have engaged in consensual commercial dealings in Pinal County, and have purposefully availed themselves of the advantages of conducting business with and within Pinal County.

8. Costco Wholesale Corporation d/b/a Costco Pharmacies

78. Defendant Costco Wholesale Corporation ("Costco") is a Delaware corporation with its principle place of business located at 999 Lake Drive in Issaquah, WA, 98027. At all times relevant to this action, Costco owned and operated chain pharmacies that, on information and belief, dispensed prescription opioids to Pinal County patients in violation of Arizona laws and regulations regarding the dispensing of such prescriptions. On information and belief, these opioids were distributed to Pinal County patients by several Costco Pharmacies, including: Costco Pharmacy # 436, located at 1445 West Elliot Road, Tempe, Arizona 85284; Costco Pharmacy # 481, located at 1415 North Arizona Avenue, Gilbert, Arizona 85233; and Costco Pharmacy # 1028, located at 1444 South Sossaman Road, Mesa, Arizona 85209. On information and belief, Costco and its pharmacies—while located outside of Pinal County—have been and continue to be frequently visited by many Pinal County patients seeking to have their opioid prescriptions filled, are top dispensers of opioids to Pinal County patients, and have committed and continue to commit serious and flagrant violations regarding—inter alia—their recordkeeping and other obligations under Arizona law in connection with dispensing opioids to Pinal County patients. As such, Costco and its pharmacies have engaged in consensual commercial dealings in Pinal County, and have purposefully availed themselves of the advantages of conducting business with and within Pinal County.

9. Walmart

79. Defendant Walmart Inc. f/k/a Wal-Mart Stores, Inc. ("Walmart") is a Delaware

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corporation with its principle place of business in Arkansas. At all times relevant to this action, Walmart distributed prescription opioids throughout the United States, including in Arizona and Pinal County specifically. On information and belief, these opioids were distributed to Pinal County by at least two Walmart entities: Wal-Mart Pharm Warehouse #32 (located at 2252 North 8th Street in Rogers, Arkansas) and Wal-Mart Pharm Warehouse #45 (located at 2250 North 8th Street, Suite 102-A in Rogers, Arkansas)—to five buyers located in Pinal County: Wal-Mart Pharmacy 10-1218, based in Casa Grande, Arizona; Wal-Mart Pharmacy 10-1381, based in Apache Junction, Arizona; Wal-Mart Pharmacy 10-2778, based in Coolidge, Arizona; Wal-Mart Pharmacy 10-3751, based in San Tan Valley, Arizona; and Wal-Mart Pharmacy 10-4430, based in Maricopa, Arizona. On information and belief, Walmart and its pharmacies are top dispensers of opioids in Pinal County that have committed and continue to commit serious and flagrant violations regarding—inter alia—their recordkeeping and other obligations under Arizona law in connection with dispensing opioids to Pinal County patients. Walmart and its pharmacies have engaged in consensual commercial dealings in Pinal County, and have purposefully availed themselves of the advantages of conducting business with and within Pinal County.

E. Prescriber Defendants

80. Defendant Takyar is a formerly licensed Medical Doctor who for years treated and prescribed opioids to Pinal County patients. In October of 2017, Defendant Takyar's authority to prescribe opioids was revoked, on the grounds that he overprescribed opioids in violation of Arizona medical practice standards. Prior to surrendering his license to practice medicine in 2018, Defendant Takyar practiced medicine and maintained a private practice in the Town of Florence, located in Pinal County. Defendant Takyar is a citizen of Mesa, Arizona. As described in further detail below in Section IV.O., Defendant Takyar facilitated the Manufacturer Defendants' scheme by—*inter alia*—routinely prescribing large amounts of oxycodone, often without performing necessary physical examinations and instead falsely documenting that such examinations were conducted.

F. DOE Defendants

81. Pinal County is ignorant of the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 1000 inclusive, and they are therefore sued herein under Rule 10(d) of the Rules of Civil Procedure for the Superior Courts of Arizona. *See* Ariz. R. Civ. Proc. 10(d). Pinal County will amend this Complaint to show their true names and capacities if and when they are ascertained. Pinal County is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

- 82. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising and unlawful, unfair, and deceptive business practices, and creating or assisting in the creation of a public nuisance in Pinal County, and the people of Pinal County through their attorneys have the right and authority to prosecute this case on behalf of the people of Pinal County.
- 83. Venue is proper in this Court because Defendants caused injury and harm to Pinal County. Some of the acts complained of also occurred in this venue. Further, Defendants conducted business and continue to do business throughout Arizona, including in Pinal County. *See* A.R.S. § 12-401(10), (18).

IV. FACTUAL ALLEGATIONS

A. Background on Pain Medicine

- 84. The practice of medicine centers on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as risk of non-treatment. Accordingly, the safe and effective treatment of chronic pain requires that a physician or other prescribing clinician be able to weigh the relative risk of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.
 - 85. Opium has been recognized as a tool to relieve pain for millennia; so has the

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magnitude of its potential for abuse, addiction, and its dangers. Opioids are related to illegal drugs like opium and heroin. In fact, types of fentanyl, a widely-distributed opioid in the United States, have now been made illegal in China.

- 86. During the Civil War, opioids gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain—particularly on the battlefield—and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States. Both the number of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.
- 87. Due to concerns about their addictive properties, opioids have been regulated as controlled substances for decades. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.
- 88. Studies and articles from the 1970s and 1980s also made the reasons to avoid opioids clear. Scientists observed poor outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing chronic pain and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, and even prohibited, the use of opioid therapy for chronic pain.
- 89. Despite the fact that opioids are now routinely prescribed, there has never been evidence of their safety and efficacy for treating chronic pain. On the contrary, evidence shows that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health condition (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.
 - 90. Opioids are highly addictive. Patients using opioids for more than a few days

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can experience severe withdrawal symptoms if they stop taking the drugs, including: anxiety, insomnia, pain, blurry vision, rapid heartbeat, chills, panic attacks, nausea, vomiting, and tremors. Opioid withdrawal can be fatal, but even when it is not fatal it can last so long and be so painful that it is difficult to stop taking opioids.

91. Putting patients on opioids puts them at risk. Patients who take opioids at higher doses and for longer periods face higher and higher risk of addiction and death. Relative to the general population, the risk of opioid-death is 35-times higher for patients receiving three consecutive months of opioid therapy. Each of the Defendants named in this Complaint disregarded the well-known and frightening statistics regarding opioid abuse and chose to ignore them in the name of profits.

B. The Manufacturer Defendants' Impact on the Perception and Prescribing of Opioids

92. Before the Manufacturer Defendants began the marketing campaign complained of herein, the generally accepted standards of medical practice dictated that opioids should only be used short-term, for acute pain, or for patients nearing the end of life. However, the Manufacturer Defendants changed this perception and took advantage of addiction to make money, effectively shifting the national discussion about pain and opioids. The Manufacturer Defendants' marketing campaign resulted in skyrocketing opioid prescriptions. The shocking increase in prescriptions has been a gold mine for the Manufacturer Defendants. It has been tragedy for patients and the people of Pinal County. Pinal County has lost citizens young and old to the opioid epidemic—too many children in Pinal County have lost their parents and too many parents have buried their children. Too many grandparents are raising their Patients who survive addiction need lengthy, difficult, and expensive grandchildren. treatment. People who are addicted to opioids are often unable to work. The addiction of parents can force their children into foster care. Babies are born addicted to opioids, a condition known as Neonatal Abstinence Syndrome ("NAS"), because they are exposed to the drugs in the womb. These babies frequently require substantial services and public assistance, including services and assistance provided by the County using its own funds.

Manufacturer Defendants' misconduct has imposed heavy costs on the people of Pinal County.

From	То
Undertreatment of Pain	Opioid Epidemic
Abuse	Addiction
Criminal	Victim
FDA	CDC
Benefits Outweigh Risks	Lack of Long-Term Evidence
ADFs as Part of Solution	ADF Value Unproven

2016 Mid-Year Board Update

C. The Manufacturer Defendants Engaged in a Deceptive Marketing Scheme to Increase Profits

- 93. To profit from their addictive drugs, the Manufacturer Defendants engaged in a deadly and illegal scheme to deceive doctors and patients. <u>First</u>, the Manufacturer Defendants deceived many prescribing clinicians and patients in Pinal County to get more people on their opioids. <u>Second</u>, the Manufacturer Defendants misled them to take higher and more dangerous doses. <u>Third</u>, the Manufacturer Defendants deceived them to stay on their drugs for longer and more harmful periods of time.
- 94. The Manufacturer Defendants targeted vulnerable people who could be introduced to opioids, including elderly patients and people who had never taken opioids before. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. Existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. Clinical

guidelines for opioid therapy therefore conclude that there are "special risks of long-term opioid use for elderly patients" and recommended that prescribers use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.

- 95. All the while, the Manufacturer Defendants peddled falsehoods to keep patients away from safer alternatives. Even when the Manufacturer Defendants knew people in Pinal County were addicted and dying, the Manufacturer Defendants treated prescribers and patients as "targets" to sell more drugs.
- 96. Each part of the scheme earned the Manufacturer Defendants more money from opioid sales and caused more addiction and death in Pinal County. And each Manufacturer Defendant participated in and profited from the scheme in Pinal County, as set forth below.
 - D. The Manufacturer Defendants Funneled Misrepresentations Through Sales Representatives, Advertisements, and Third-Parties
- 97. Pinal County patients died after taking the Manufacturer Defendants' drugs because Pinal County was subject to the Manufacturer Defendants' massive deceptive sales campaign. To spread their false and misleading statements, the Manufacturer Defendants deceptively marketed their opioids directly to doctors and patients in Pinal County. The Manufacturer Defendants also deployed sales representatives to spread their false and misleading statements about the risks and benefits of opioids for the treatment of chronic pain throughout Arizona and, specifically, in Pinal County.
- 98. These representatives were the Manufacturer Defendants' most powerful tools of deception were sending sales representatives to promote opioids to Pinal County doctors, nurses, and pharmacists face to face. During sales visits, the Manufacturer Defendants' representatives made false and misleading claims directly to the professionals who care for Pinal County patients. The Manufacturer Defendants assigned representatives to Pinal County and gave them lists of Pinal County doctors to visit. The 'scripts' used by these representatives were approved and closely monitored by the Manufacturer Defendants.
- 99. Each of these visits cost the Manufacturer Defendants money. But the Manufacturer Defendants made this money back many times over, because they misled

healthcare providers in and around Pinal County to prescribe the Manufacturer Defendants' addictive drugs to Pinal County patients. The Manufacturer Defendants rewarded high prescribing doctors with meals, money, and gifts. The Manufacturer Defendants' sales representatives who generated the most prescriptions won bonuses and prizes. These representatives have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, and other healthcare providers, including those in Pinal County.

- 100. The Manufacturer Defendants' representatives have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by regulators required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."
- 101. The Manufacturer Defendants also conducted and continue to conduct advertising campaigns touting the purported benefits of their opioids. For example, the Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.
- 102. A number of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, since at least May 21, 2011, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year old writer with osteoarthritis

of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arizona.

103. Similarly, despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain and other off-label pain conditions. As of June 2012, Insys defined BTP in cancer patients to include mild pain: a "flare of mild-to-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Dr. Russell Portenoy. In Insys trained and instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

104. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others, including dentists and podiatrists, writing prescriptions as well.¹⁹

105. On September 6, 2017, Senator Claire McCaskill's report, "Fueling an Epidemic: Insys Therapeutics and the System Manipulation of Prior Authorization" was published. Citing to "internal Insys" information, the report describes how Insys "apparently lacked even basic measures to prevent its employees from manipulating the prior authorization process," and that—despite "receiv[ing] clear notice of these deficiencies"—Insys maintained its "significant efforts . . . to reduce barriers to the prescription of Subsys, . . . includ[ing] actions to mislead pharmacy benefit managers ("PBMs") about the role of Insys in the prior

Portenoy's paper, which was featured in the 1990 issue of Pain, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity—i.e., to an intensity of 'severe' or 'excruciating')... on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 41(3) Pain 273-81 (July 1990).

¹⁹ Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. TIMES (May 13, 2014), https://www.nytimes.com/2014/05/14/business/doubts-raised-aboutoff-label-use-of-subsys-a-strong-painkiller.html.

authorization process and the presence of breakthrough cancer pain in potential Subsys patients."²⁰

106. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

"The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out these messages were exaggerations at best and outright lies at worst.

* * *

"Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed." ²¹

107. Less than two years later, Insys' former chief executive officer (Defendant Babich) pleaded guilty to participating in a nationwide scheme to bribe doctors in exchange for prescribing Subsys,²² and Insys' founder and majority shareholder (Defendant Kapoor) was found guilty for his part in this scheme.²³ The Arizona Attorney General, Mark Brnovich, has also filed a lawsuit against Insys in connection with a kickback scheme where Insys paid bribes in the form of sham "speaker fees" to Arizona physicians in exchange for the

²⁰ Prior authorization (PA) is any process by which physicians and other health care providers must obtain advance approval from a health plan before a specific procedure, service, device, supply or medication is delivered to the patient to qualify for payment coverage. (American Medical Association, *Prior authorization: The current landscape*, p. 1 (2015), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/psa/prior-authorization-toolkit_0.pdf.

²¹ See, LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable, Sep. 12, 2017, at 31:03-31:37, https://www.youtube.com/watch?v=k9mrQa8_vAo (last accessed Mar. 17, 2019).

²² Nate Raymon, Former Insys CEO pleads guilty to opioid kickback scheme, REUTERS (Jan. 9, 2019), https://www.reuters.com/article/us-insys-opioids/former-insys-ceo-pleads-guilty-to-opioid-kickback-scheme-idUSKCN1P312L.

²³ Emanuel, Gabrielle, *Opioid Executive John Kapoor Found Guilty in Landmark Bribery Case* (May 2, 2019) https://www.npr.org/2019/05/02/711346081/opioid-executive-john-kapoor-found-guilty-in-landmark-bribery-case.

physicians prescribing Subsys.²⁴

108. The Manufacturer Defendants²⁵ also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by the Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

109. Each Manufacturer Defendant devoted and continues to devote massive resources to direct sales contacts ("detailing") with doctors. In 2014 alone, the Manufacturer Defendants spent \$168 million on detailing branded opioids to doctors. This amount is twice as much as the Manufacturer Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo, and \$2 million by Actavis.

110. The Manufacturer Defendants also deceptively marketed opioids in Arizona through unbranded advertising—*i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly

AG Brnovich Files Lawsuit Against Opioid Manufacturer Insys Therapeutics and Three Arizona Doctors, AZAG.gov (Aug. 31, 2017), https://www.azag.gov/press-release/ag-brnovich-files-lawsuit-against-opioid-manufacturer-insys-therapeutics-and-three.

Upon information and belief, Actavis continued to carry out speaker programs after it acquired Kadian.

promote opioids for the treatment of chronic pain.²⁶

advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by regulators. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

112. The Manufacturer Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by regulators. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
"People who take opioids as prescribed usually do not become addicted."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use."

113. The Manufacturer Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by the Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." The Manufacturer Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or present continuing medical education programs ("CMEs"), and their support helped

The phrase "acted in concert" includes conspiring to achieve some end and aiding and abetting in the commission of acts necessary to achieve some end.

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these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the Manufacturer Defendants.

Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use for chronic pain. The Manufacturer Defendants know that doctors and other prescribing clinicians rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for long-term opioid therapy for chronic pain. For example, the New York Attorney General ("NY AG") found in its settlement with Purdue that through March 2015, the Purdue website, "In the Face of Pain," failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. The Manufacturer Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, the Manufacturer Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

115. The Manufacturer Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. The Manufacturer Defendants were able to direct and exert control over each of these activities through their KOLs. Indeed, regulators now recognize that treatment guidelines can "change

prescribing practices."

116. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups"—which include, but are not limited to, the American Pain Foundation ("APF") and the American Academy of Pain Medicine—generated treatment guidelines, unbranded materials, and programs that favored opioid therapy for chronic pain. These guidelines, materials, and programs were not supported by the evidence at the time they were created, and they are not supported by the scientific evidence today. These Front Groups also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

- 117. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. For example, Purdue's consulting agreement with APF gave it direct, contractual control over APF's work. In doing so, the Manufacturer Defendants made sure that the Groups would generate only the messages the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain or doctors treating those patients.
- 118. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, the Manufacturer Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Endo, Janssen/J&J, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among

other projects, PCF worked to ensure that a legally mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing. PCF also worked to address a perceived "lack of coordination" among its members and developed "key" messages that were disseminated in programs and industry-run websites.

E. The Manufacturer Defendants Deceived Healthcare Providers and Patients to Get More People on Highly Addictive Opioids, at Higher Doses, for Longer Periods

119. To convince prescribers and patients around the country, including in the State of Arizona and Pinal County, that opioids can and should be used to treat chronic pain, the Manufacturer Defendants had to convince them that long-term opioid use is both safe and beneficial for chronic pain. The Manufacturer Defendants chose to proceed by deceiving those prescribers and patients about the risks and benefits of long-term opioid use. The Manufacturer Defendants, through Front Groups, KOLS, and advertisements, made claims that were not supported by or were contrary to the scientific evidence—most frequently, these claims downplayed the risks of addiction in order to convince providers and patients alike that prescription opioids should be used more regularly. Even though pronouncements by and guidance from regulators based on that evidence confirm that their claims were false and misleading, Pinal County is informed and believes the Manufacturer Defendants have not corrected them and continue to spread them today, including as set forth specifically below.

1. Deception About Addiction

120. The Manufacturer Defendants always knew that their opioids carry grave risks of addition and death. Instead of being honest about these risks, the Manufacturer Defendants obscured them, including by falsely stating and implying that "appropriate patients" won't get addicted. To convince prescribers and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by regulators and the medical community at large.

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First, the Manufacturer Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and misleading claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011 are described below:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.
- b. Purdue and Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft.
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."
- d. Endo and Cephalon distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.
- e. Janssen/J&J reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."
- f. Janssen ran a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."
- g. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]."

h.	Detailers for Purdue, Endo, Teva and Janssen in Arizona have minimized or
	omitted and continue to minimize or omit any discussion with doctors or
	their medical staff in Arizona, including Pinal County, about the risk of
	addiction; falsely claiming that abuse-deterrent formulations "cannot be
	crushed," effectively downplaying the potential that these opioids would be
	abused; and routinely did not correct the misrepresentations noted above.

- 122. Moreover, Purdue, in a pamphlet for doctors, *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substance Prescribing Practices*, wrote that addiction "is not caused by drugs." Instead, Purdue assured doctors that addiction happens when the wrong patients get drugs and abuse them: "it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse."²⁷
- 123. Purdue also promoted its opioids to Pinal County patients with marketing that was designed to obscure the risk of addiction and even the fact that Purdue was behind the campaign. Purdue created a website, *In the Face of Pain*, that promoted pain treatment by urging patients to "overcome" their "concerns about addiction." Testimonials on the website that were presented as personal stories were in fact by Purdue consultants, whom Purdue had paid tens of thousands of dollars to promote its drugs.²⁸
- 124. Another Purdue publication, the *Resource Guide for People with Pain*, falsely assured patients and doctors that opioid medications are not addictive:

"Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken as directed, these medications give relief – not a 'high'."²⁹

125. Pursue falsely denied the risk of addiction, falsely implied that addiction requires patients to get "high," and falsely promised that patients would not get addicted if they took opioids as prescribed.

²⁷ Purdue Pharma LP, *Providing Relief, Preventing Abuse* (2008), pg. 12; *see also* K. Nelson, *Purdue Pharma lawsuit: Terms you need to know to understand OxyContin blitz*, Knox News (Jul. 13, 2018), https://www.knoxnews.com/story/news/health/2018/07/13/purdue-pharma-lawsuit-terms-know-understand-oxycontin-blitz/779173002/.

²⁸ Purdue Pharma LP, *In the Face of Pain* (Oct. 24, 2011).

- 126. Purdue funded and distributed many more publications that were similarly misleading. For example, *Exit Wounds* misleadingly claimed that "[1]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."³⁰
- 127. Responsible Opioid Prescribing told doctors that only a "small minority of people seeking treatment may not be reliable or trustworthy" and not suitable for addictive opioid drugs.³¹
- 128. Similarly, while Janssen/J&J repeatedly disclaimed responsibility for its part in causing the opioid crisis, insisting that "[e]verything that we have done with our products when we've promoted opioid products . . . was appropriate and responsible," internal memoranda and communications between high-level executives at Janssen show the company funded and pushed bogus research to lend false credibility to a series of dangerous fictions, claiming that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain," and enabling "Janssen's representatives [to] promote[] Nucynta and Nucynta ER as safer, milder, and less addictive than competitor opioids like OxyContin."³²
- 129. In 2017, Mallinckrodt agreed to settle for \$35 million allegations regarding excessive sales of oxycodone in Florida. According to these allegations, even though Mallinckrodt knew that its oxycodone was being diverted to illicit use, it nonetheless continued to incentivize and supply these suspicious sales, and it failed to notify regulators of the suspicious orders in violation of Mallinckrodt's legal obligations. Similarly, in 2008, Cephalon pleaded guilty to criminal violations for its misleading promotion of Actiq and two other drugs, and agreed to pay \$425 million.

²⁹ Purdue Pharma LP, Resource Guide for People with Pain, p. 8 (2009).

³⁰ Purdue Pharma LP, Exit Wounds, p. 107 (2009).

³¹ Purdue Pharma LP, *Responsible Opioid Prescribing*, p. 11 (2007).

M. Aron, *deceptively marketing opioids*, NJTV News (Nov. 13, 2018), https://www.njtvonline.org/news/video/state-sues-johnson-johnson-subsidiary-for-deceptively-marketing-opioids/.

- 130. In August 2019, Johnson & Johnson was found liable of: (a) having engaged in false and misleading marketing of both their drugs and opioids more generally; and (b) creating, contributing to, and perpetuating a public nuisance under Oklahoma law. This determination resulted in a \$572 million verdict that represent just one year of abatement expenses in one state.
- 131. Over and over, Defendants said opioids could be given to "trusted" patients without risk of addiction. To promote their drugs, the Manufacturer Defendants pushed the myth that addiction is a character flaw, and "trustworthy" people do not get addicted to drugs.
- 132. These claims are contrary to longstanding scientific evidence and recently established clinical guidelines for opioid therapy. These guidelines provide that there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The guidelines indicate that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."
- addiction was further exposed when regulators announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. These announcements emphasized that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." Thus, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," regulators and the medical community at large emphasize that opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. These regulators further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."
- 134. The New York Attorney General, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated

outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed until at least April 2012 on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. On information and belief, Endo made similar misrepresentations to healthcare providers and patients in the State of Arizona and Pinal County. However, Endo has not yet been restricted from making these statements in Arizona.

2. Deception to Get Vulnerable Patients on Opioids

with opioids, with up to 40% of chronic pain patients treated in specialty and primary care

135. To expand the market for opioids, the Manufacturer Defendants also trained their representatives to target vulnerable populations and encourage doctors to put them on opioids, without disclosing the risks. The Manufacturer Defendants deceptively promoted opioids for elderly patients, patients who had never taken opioids, and patients with osteoarthritis—putting thousands more patients at risk.

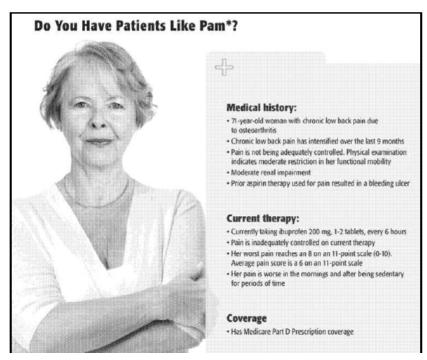
Elderly Patients

136. The Manufacturer Defendants knew that prescribing opioids to elderly patients increase their risk of death. Elderly patients are at greater risk of dangerous interactions between drugs. They are also at a greater risk of respiratory depression—in which patients suffocate and die. But the Manufacturer Defendants saw the opportunity to earn millions of dollars by getting elderly patients on opioids because the public would pay through Medicare. For instance, Purdue's internal documents show it targeted "Patients over the age of 65 as more coverage is achieved."³³

Opioid-Naïve Patients

137. The Manufacturer Defendants also targeted patients who were not already taking opioids, described in the field as "opioid-naïve." The Manufacturer Defendants unfairly and

- 138. For instance, Purdue trained its sales reps to promote their drugs specifically for opioid-naïve patients. In training calls, Purdue managers instructed:
 - "Your opportunity here is with the naïve community, let's use the naïve trial to make the case."
 - "You created an epiphany with the doctor today (potentially) by reviewing the opiate naïve patient profile. What made him more apt to write this for his patient, being an amiable doctor, is the fact that he would not have to talk patients out of their short-acting [opioids]."
 - "This was an example of what a good call looks like . . . [Dr.] was particularly interested in the RM case study of Marjorie, which generated a robust discussion of opioid naïve patients"
- 139. Purdue also promoted its drugs for opioid-naïve patients using the deceptive term "first line opioid." "First line" is a medical term for the preferred first step in treating a patient. Opioids are not an appropriate first line therapy.



patients by

targeting prescribers with the least training in the risks of opioids. The Manufacturer

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³³ Purdue Pharma LP, *Pain Products Presentation*, p. 12 (Jan. 28, 2015).

Defendants determined that nurse practitioners, physician assistants, and primary care doctors were especially responsive to sales reps, so the Manufacturer Defendants targeted them to sell more drugs.

- 141. The Manufacturer Defendants knew or should have known that opioids were not appropriate to treat nonmalignant pain in non-cancer patients, including patients suffering from osteoarthritis. Opioids are not approved to treat osteoarthritis. For instance, Purdue conducted a single study on osteoarthritis for Butrans, and it failed. Purdue admitted in internal documents that its opioids "are not indicated for a specific disease" and "it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis."
- 142. Nevertheless, to meet their business goals, the Manufacturer Defendants trained their sales representatives to mislead healthcare providers and patients by promoting opioids for osteoarthritis. For instance, a Purdue marketing presentation concluded that its sales reps were "identifying appropriate patients" because osteoarthritis was specifically mentioned during at least 35% of sales visits.
- 143. The Manufacturer Defendants also directed their sales reps to use marketing materials that highlight patients with osteoarthritis, even though their drugs were never indicated for that disease.

3. The Manufacturer Defendants Deceived Doctors and Patients to Use Higher and Higher Doses

144. The impetus behind the Manufacturer Defendants' scheme is as simple as it is nefarious. Enticed by the exponentially greater profits that would result from increases in opioid dose mix, the Manufacturer Defendants deceived prescribing medical practitioners and patients across the nation—including practitioners and patients in the State of Arizona and Pinal County—about the risks and benefits of opioids for the long-term treatment of chronic pain. The Manufacturer Defendants dishonestly encouraged (or even bribed) these practitioners to provide long-term opioid therapy to patients for whom such treatment was not

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clinically appropriate, such as patients suffering from long-term chronic pain due to osteoarthritis. As set forth below, the Manufacturer Defendants' deceptive scheme was wildly successful, effectively increasing the supply of opioids in Plaintiff's territory and drowning Plaintiff's community in a sea of highly addictive prescription drugs.

145. The Manufacturer Defendants—including, but not limited to, Defendants Endo,

Janssen, Mallinckrodt and Cephalon—also falsely instructed prescribing clinicians and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction"—a made-up, misleading and scientifically unsubstantiated term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, Teva, and Purdue. Through aggressive marketing campaigns to prescribers and patients—including prescribers and patients in Pinal County—the Manufacturer Defendants used the concept of "pseudoaddiction" as a lever to mislead prescribers and their patients into believing that certain warning signs of opioid addiction³⁴ were neither indicative of "true" addiction, nor cause for alarm. To the contrary, the Manufacturer Defendants repeatedly claimed that drug-seeking behavior was a manifestation of undertreated pain, which should be addressed by prescribing even more opioids. Importantly, at all times relevant to this action, the Manufacturer Defendants both knew the concept of pseudoaddiction was false and yet actively sought to conceal the truth from healthcare providers and patients in Pinal County, effectively sabotaging these prescribers' ability to protect their patients from opioid addiction and concomitant injuries and make informed decisions about whether or not opioids were appropriate for their patients. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants are described below:

a. Purdue, Cephalon and Endo sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name",

³⁴ *E.g.*, demanding more opioids, engaging in manipulative behavior to obtain drugs, requesting specific drugs, hoarding drugs during periods of reduced symptoms, using drugs for unapproved purposes, etc.

"demanding or	manipulative	behavior,"	seeing	more	than	one d	octo	r to
obtain opioids,	and hoarding,	are all sign	s of pse	eudoad	ldictio	n, rat	her t	han
true addiction.	This publication	on remains	for sale	online	e.			

- b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction...refers to patient behaviors that may occur when pain is under-treated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Purdue sponsored a CME program entitled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse" in 2011. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.
- f. Detailers for Purdue have directed doctors and their medical staffs in Arizona, including Pinal County, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.
- g. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (emphasis added.)
- 146. The medical community now rejects the concept of pseudoaddiction, and does not recommend that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, widely accepted opioid treatment guidelines now provide that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to

experience pain relief with longer-term use," and that prescribing clinicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

147. Even one of the Manufacturer Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.' "35" Consistent with this testimony, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York. 36

148. The Manufacturer Defendants also falsely told doctors and patients that addiction risk screening tools, such as patient contracts, urine drug screens, and similar strategies, would both allow prescribers to reliably identify and safely prescribe opioids to patients who were predisposed to (or exhibited warnings signs of) opioid addiction and misuse, as well as be efficacious enough to essentially rule out the risks of such addition and misuse—even for patients receiving long-term opioid therapy. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after March 21, 2011 are described below:

a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The

In the Matter of Endo Health Solutions Inc. *et al*, Assurance No. 15-228, p. 7, ¶ 23 (NY AG, Mar. 1, 2016), https://www.ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

Id., p. 15, ¶ 41.e.

supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

- b. Purdue sponsored a November 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."
- c. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients and not opioids are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.
- d. Since at least May 21, 2011, detailers for Purdue have touted and continue to tout to doctors in Arizona, including Pinal County, the reliability and effectiveness of screening or monitoring patients as a tool that would virtually eliminate the risks of opioid abuse and addiction.
- 149. Consistent with what the Manufacturer Defendants already knew—but failed to disclose—at all times relevant to this action, opioid treatment guidelines now confirm that the Manufacturer Defendants' statements were false, misleading, and unsupported at the time they were made by the Manufacturer Defendants. These guidelines note that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—"for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, opioid treatment guidelines now recognize that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsel that prescribers "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

4. The Manufacturer Defendants Peddled Falsehoods to Keep Patients Away from Safer Alternatives

A. Deception about Lower-Dose Opioids

150. The Manufacturer Defendants deceptively claimed that its opioids provided

more effective pain relief than traditional immediate-release opioids (sometimes called "IROs"). For instance, Purdue's records show that the sales reps repeatedly claimed that OxyContin's "steady state is better than peak and trough w/ [IROs]." Purdue claimed that OxyContin provides a "full tank of gas," but immediate-release opioids require "stopping at each exit to refuel." Purdue bolstered these misrepresentations with marketing materials that misrepresented data to indicate that Purdue drugs provided more consistent pain relief than more frequently dosed, lower-dose opioids. On information and belief, each of the Manufacturer Defendants engaged in similarly illegal and deceptive conduct regarding the deception about lower-dose opioids.

B. Deception about Quality of Life

151. The Manufacturer Defendants also steered patients away from safer alternatives with the false claim that its opioids improve patients' "quality of life." For instance, Purdue's internal documents admit that "Purdue has no clinical studies or other substantial evidence demonstrating that a Purdue Product will improve the quality of a person's life." Nevertheless, Purdue sales reps repeatedly claimed that its opioids improve quality of life. Purdue also devised and funded third-party publications to say that opioids give patients the "quality of life we deserve." On information and belief, each of the Manufacturer Defendants engaged in similarly illegal and deceptive conduct regarding the deception about quality of life.

C. Deception about Risk of Abuse

152. In addition to visiting prescribers and pharmacists hundreds of thousands of times, the Manufacturer Defendants distributed thousands of copies of its deceptive publications, including *Providing Relief*, *Preventing Abuse*; *Resource Guide for People with Pain*; *Exit Wounds*; *Opioid Prescribing*: *Clinical Tools and Risk Management Strategies*; *Responsible Opioid Prescribing*; and *Clinical Issues in Opioid Prescribing*. *Purdue's In The Face of Pain*.

5. The Manufacturer Defendants Downplayed Opioids Withdrawal

153. To downplay the risk and impact of addiction and make doctors feel more

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comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use. For example, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent* Pain in the Older Adult, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur. This publication was available on APF's website until the organization dissolved in May 2012. And detailers for Janssen have told and continue to tell prescribers in Arizona, including prescribers in Pinal County, that their patients would not experience withdrawal if they stopped using opioids.

- 154. The Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal that, per widely accepted opioid treatment guidelines, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, rapid heartbeat, spontaneous abortion and premature labor in pregnant women, and the unmasking or exacerbating of anxiety, depression, and addiction.
- 155. The Manufacturer Defendants also grossly understated the difficulty of tapering, particularly after long-term opioid use. Widely accepted opioid treatment guidelines now emphasize that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." These guidelines further state that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. Likewise, regulators have acknowledged the lack of any "high-quality studies comparing the

effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

156. Some prescribers and many patients in Pinal County relied on the truth of the Manufacturers Defendants' representations about both the benefits of opioid analgesics and the risks of opioid addiction. Because each of the Manufacturer Defendants willfully concealed the truth about their products and knew their representations were false at the time they were made, Pinal County's citizens are forced to pay the price for Defendants' misconduct.

6. The Manufacturer Defendants Hid the Greater Risks to Patients at Higher Dosages of Opioids

- 157. The Manufacturer Defendants were in the best position to know, and in fact did know, that—relative to the general population—the risk of opioid-related death increases exponentially after a patient takes opioids for several consecutive months.
- 158. Specifically, the Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011 are described below:
 - a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
 - b. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need"

a larger dose of an opioid, regardless of the dose currently prescribed.
The guide stated that opioids have "no ceiling dose" and are therefore
the most appropriate treatment for severe pain. ³⁷

- c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain." The website was still accessible online after May 21, 2011.
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."
- e. Janssen sponsored a patient education guide entitled *Finding Relief:* Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. Through March 2015, Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.
- h. Purdue sponsored a CME entitled Overview of Management Options that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

³⁷ The Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See, e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids); *Finding Relief: Pain Management for Older Adults* (Janssen) (NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation).)

- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.
- j. Since at least May 21, 2011, Purdue's detailers have told doctors in Arizona, including in Pinal County, that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.
- 159. Through a series of internal strategy presentations and other communications with its sales force and prescriber-accomplices, Purdue aimed to "drive" patients toward higher doses of opioids for longer periods by dramatically increasing the supply. Apparently unsatisfied with a supply-centric strategy, however, Purdue also sought to increase consumer demand for opioids, namely by offering discounts to patients on their first prescriptions. These discounts ultimately proved to be one of Purdue's most powerful tactics to keep patients on opioids longer, as Purdue's return on investment from these discounts was a staggering 4.28—*i.e.*, every \$1,000,000 Purdue gave away in first-time patient discounts came back to Purdue as \$4,280,000 in revenue.

Drive appropriate titration and length of therapy with continuing patients, to maintain total Kg within 2% of forecast

Purdue internal strategy presentation from 2012

160. These claims conflict with the scientific evidence, as confirmed by widely accepted opioid treatment guidelines. These guidelines explain that the "[b]enefits of high-dose opioids for chronic pain are not established," and the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, these guidelines explain that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." Opioid treatment guidelines also provide that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages," because "the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." Specifically, the clinical research "appear[s] to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose

mortality." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain. In light of this evidence, prescribing clinicians are now advised to "avoid increasing dosages" above 90 morphine milligram equivalents ("MMEs") per day.

- 161. Finally, the Manufacturer Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.
- 162. These abuse deterrent formulations ("AD opioids") are harder (but not impossible) to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Though at all times relevant to this action the Manufacturer Defendants falsely claimed that AD opioids "cannot be crushed," these claims were conclusively debunked by a 2015 study, finding that AD opioids are, in fact, "not impossible" to abuse. They can be defeated—often quickly and easily—by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.
- 163. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, regulators have admonished the Manufacturer Defendants that any communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health.³⁸
 - 164. Despite this admonition, the Manufacturer Defendants have made and continue

 $|^{38}$ *Ibid*.

to make	misleading	claims about	the extent to	o which the	eir AD opioi	ids can preven	t or reduce
abuse a	nd addiction						

less prone to misuse and abuse since at least May 21, 2011 even though: (1) Endo's petition to approve Opana ER as abuse-deterrent was rejected in 2012; (2) regulators found in 2013 that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed—contrary to Endo's claims about Opana ER's abuse-deterrent properties. Indeed, Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that Opana ER could not be crushed, creating the impression that the drug was more difficult to abuse. On information and belief, detailers for Endo continue to reiterate these false statements to Arizona prescribers and patients, including prescribers and patients in and around Pinal County.

166. In the 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

- 167. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in 2017, regulators requested that Endo withdraw Opana ER from the market.
- 168. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—*i.e.*, reformulated Oxycontin and Hysingla—since at least May 21, 2011. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, numerous Arizona prescribers report that detailers from Purdue have regularly used

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the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

- 169. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the label for Purdue's AD opioids—which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.
- 170. To the contrary, testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other opioid products.
- 171. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was

reduced, those addicts simply shifted to other drugs such as heroin.³⁹ Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

- 172. Similarly, widely accepted clinical guidelines for opioid therapy state that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Regulatory agencies have further reported that their staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."
- 173. These false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, the Manufacturer Defendants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Indeed, Purdue has conveyed that its sale of AD opioids is "atonement" for its earlier sins even though its true motive was to preserve the profits it would have lost when its patent for OxyContin expired. Purdue introduced its first AD opioid days before that patent would have expired and petitioned regulators to withdraw its non-AD opioid as unsafe and; thereby, prevent generic competition. Second, these claims are falsely targeting doctors and other prescribing clinicians' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraging these clinicians to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing prescribing clinicians to prescribe more AD opioids—which are far more expensive than other opioid products even though they provide little or no additional benefit.

³⁹ Cicero, Theodore J., and Matthew S. Ellis, *Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin*, 72.5 JAMA Psychiatry, 424-30 (2015).

⁴⁰ Perrone, *Drugmakers push profitable*, *but unproven*, *opioid solution*, The Associated Press (Dec. 15, 2016), https://publicintegrity.org/state-politics/drugmakers-push-profitable-but-unproven-opioid-solution.

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174. These numerous, longstanding misrepresentations of the risks and benefits of long-term opioid use spread by Defendants successfully convinced prescribing clinicians and patients to mistakenly discount those risks.

7. The Manufacturer Defendants Grossly Overstated the Benefits of **Chronic Opioid Therapy**

To convince doctors and patients that opioids should be used for the long-term 175. treatment of chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. However, widely accepted clinical guidelines for opioid therapy now make clear that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, these guidelines found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

Likewise, regulators recognize the lack of evidence to support long-term opioid use. In 2013, for instance, one regulator stated it was "not aware of adequate and wellcontrolled studies of opioids use longer than 12 weeks." Despite this, the Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. On information and belief, not only have the Manufacturer Defendants failed to correct these false and misleading claims, they continue to make them today in the State of Arizona and in Pinal County.

- For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011 are described below:
 - a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

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- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal."
- d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.
- e. Responsible Opioid Prescribing (2007), sponsored and distributed by Endo, Cephalon and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.
- f. Purdue and Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."
- g. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

- j. Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients."
 k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER,
 - k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that government statistics do not take into account that patients could be driven to suicide without pain relief.
 - 1. Since at least May 21, 2011, Purdue's, Endo's, Teva's and Janssen's sales representatives have conveyed and continue to convey to prescribers in Arizona, including in Pinal County, the message that opioids will improve patient function.
- 178. These claims find no support in the scientific literature. Regulators and industry stakeholders have made this clear for years. Most recently, widely accepted clinical guidelines for opioid therapy concluded "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." As illustrated below, this conclusion is reinforced throughout these guidelines:
 - "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
 - "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
 - "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."
- 179. Industry guidelines for opioid therapy also note that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

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180. Consistent with these guidelines, regulators have also repudiated Defendants' claim that opioids improved function and quality of life. In 2010, for instance, regulators warned Actavis, in response to its advertising described above, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." And in 2008, regulators sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

The Manufacturer Defendants also falsely and misleadingly emphasized or 181. exaggerated the risks of competing products like NSAIDs, so that prescribing clinicians and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants, before and after May 21, 2011, have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, based on the scientific evidence, these misrepresentations by the Manufacturer Defendants contravene widely accepted clinical guidelines for opioid therapy as well as pronouncements by and guidance from regulators. Indeed, the labels for ER/LA opioids in 2013 and IR opioids in 2016 were changed to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And widely accepted clinical guidelines for opioid therapy state that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

8. The Manufacturer Defendants Also Engaged in Other Unlawful and **Unfair Misconduct**

182. Since at least 2010, Purdue's sales representatives have pressed doctors to prescribe its opioids in order to be rewarded with talks paid by Purdue.

183. Although regulators have repeatedly informed Purdue about its legal "obligation to design and operate a system to disclose . . . suspicious orders of controlled substances" and to inform regulators "of suspicious orders when discovered," Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs after 2010, despite knowing about it for years.

184. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors in Arizona and could identify Arizona doctors and other prescribing clinicians who displayed red flags. Using this information, Purdue has maintained a database since 2002 of prescribing clinicians suspected of inappropriately prescribing its drugs. Rather than report these clinicians to regulators such as state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade regulators to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused.

185. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action—even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite Purdue's knowledge of illegal prescribing, Purdue did not report until after law enforcement shut down clinics that overprescribed OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

186. This misconduct by Purdue is ongoing. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.

187. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health

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Services, said in a Los Angeles Times article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers in Arizona, including in Pinal County.

Like Purdue, Defendant Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids after May 21, 2011, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

F. Although the Manufacturer Defendants Knew That Their Marketing of Opioids Was False and Misleading, They Fraudulently Concealed Their Misconduct

189. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. Regulators warned the Manufacturer Defendants of this, and Purdue entered into settlements in the hundreds of millions of dollars to address similar misconduct that occurred before 2008. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of

addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, regulators have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

- 190. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.
- 191. The Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.
- 192. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the Manufacturer Defendants' deceptive

messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Plaintiff.

- 193. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.
- 194. As detailed in allegations below, the Sacklers were intimately aware of the potential liabilities against the Purdue entities because the Sacklers controlled the companies. The Sacklers personally participated in the misconduct or at least acquiesced to the misconduct by way of their knowledge of the wrongful acts combined with their failure to act. The Sacklers also performed multiple fraudulent transfers of billions of dollars to enrich themselves while leaving the Purdue entities hopelessly undercapitalized if ever forced to pay for the injuries they had caused.
 - G. By Knowingly Causing an Explosion in Opioid Prescribing, Use, Misuse, Abuse, and Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair Business Practices, Each Manufacturer Defendant Has Created or Assisted in the Creation of a Public Nuisance in Pinal County
 - 1. The Manufacturer Defendants' Deceptive Marketing Scheme Has
 Caused and Continues to Cause a Huge Increase in Opioid
 Prescriptions and Use in Pinal County
- 195. The Manufacturer Defendants' misrepresentations deceived and continue to deceive doctors and patients in Pinal County about the risks and benefits of long-term opioid use. Studies also reveal that some doctors and many patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids

were potentially addictive. Indeed, Arizona residents in treatment for opioid addiction, including citizens of Pinal County, confirm that they were never told that they might become addicted to opioids when they started taking them, were told that they could easily stop using opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

- 196. The Manufacturer Defendants knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.
- 197. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices caused and continue to cause doctors and other clinicians in Pinal County to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent the Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.
- 198. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices also caused and continue to cause patients in Arizona, including patients in Pinal County, to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them. The Manufacturer Defendants' deceptive marketing and their unlawful and unfair business practices have caused and continue to cause the prescribing and use of opioids to explode in Pinal County.
- 199. In Pinal County, the Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of their opioids during the past few years has been particularly effective. For example, one survey reports that pain specialists were more likely to recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent

properties were using more of it than those who did not know it was an AD opioid. Although sales of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales revenue (\$2.4 billion or approximately 25% in opioid sales revenue in 2015).

- 200. The dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in the Manufacturer Defendants' spending on their deceptive marketing scheme. The Manufacturer Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.
 - 2. By Causing an Explosion in Opioid Prescriptions and Use, the Manufacturer Defendants Have Created or Assisted in the Creation of a Public Nuisance in Pinal County
- 201. The escalating number of opioid prescriptions written by doctors who were deceived by the Manufacturer Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Arizona, including in Pinal County.
- 202. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."
- 203. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors [m]any of [whom] were even taught incorrectly that opioids are not addictive when prescribed for legitimate pain."
- 204. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. A 2016 report explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."

Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the report concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

205. Contrary to the Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous prescribing clinicians and substance abuse counselors in Arizona note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

206. As regulators observed in 2016, the opioid epidemic is getting worse, not better. The overprescribing of opioids for chronic pain caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Arizona who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS"). These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts.

207. The Manufacturer Defendants' creation, through false and misleading advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed Pinal County. The Manufacturer Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors and other prescribing clinicians' prescriptions.

- 208. The rise in opioid addiction caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids.
 - 209. Many patients who become addicted to opioids will lose their jobs. Some will

lose their homes and their families. Some will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.

- 210. Absent each Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, the public health crisis caused by opioid misuse, abuse, and addiction in Pinal County, would have been averted or much less severe.
- 211. These harms in Pinal County, caused by the Manufacturer Defendants' deceptive marketing schemes and unlawful and unfair business practices are a public nuisance because they are "injurious to health" and interfere "with the comfortable enjoyment of life" and "property," and because they "affect[] at the same time" "entire communit[ies]" and "neighborhoods" and "any considerable number of persons." A.R.S. 13-2917(A).
 - 3. The Manufacturer Defendants Knew and Should Have Known That
 Their Deceptive Marketing Schemes Would Create or Assist in the
 Creation of This Public Nuisance in Pinal County
- 212. The Manufacturer Defendants knew or should have known about these harms that their deceptive marketing and unlawful and unfair business practices have caused and continue to cause in Pinal County. The Manufacturer Defendants closely monitored their sales and the habits of prescribing clinicians, including clinicians in Pinal County. Their sales representatives, who visited clinicians and attended CMEs, knew which prescribers were receiving their messages and how they were responding. The Manufacturer Defendants also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew—and, indeed, intended—that their misrepresentations would persuade prescribing clinicians in Pinal County to prescribe, and patients in Pinal County to use, their opioids for chronic pain.

4. The Manufacturer Defendants' Conduct and Role in Creating or Assisting in the Creation of the Public Nuisance Is Not Excused by the Actions of any Third Parties

- 213. The Manufacturer Defendants' actions are not permitted nor excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. Approval of opioids for certain uses did not give the Manufacturer Defendants license to misrepresent the risks and benefits of opioids. Indeed, the Manufacturer Defendants' misrepresentations were directly contrary to both clinical guidelines for opioid therapy as well as pronouncements by and guidance from regulators.
- 214. Nor is the Manufacturer Defendants' causal role broken by the involvement of doctors and other prescribing clinicians. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source prescribing clinicians could rely on for information and prevented them from making informed treatment decisions. The Manufacturer Defendants also were able to harness and hijack what these clinicians' good intentions—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

H. The Manufacturer Defendants' Fraudulent Marketing Has Led To Record Profits

215. While the use of opioids has taken an enormous toll on Pinal County and its citizens, the Manufacturer Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in revenue for drug companies like the Manufacturer Defendants. Indeed, financial information indicates that each Manufacturer Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

I. The Sacklers Led Purdue's Misconduct

216. Arizona laws against both the creation of a public nuisance as well as unfair and deceptive conduct in commerce applies to individuals regardless of whether they are officers, directors, or employees. Holding individuals personally liable for their misconduct does not

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require piercing a corporate veil. Individuals are personally liable if: (a) they participated in the misconduct; or (b) they knew about the misconduct and failed to stop it; or (c) they should have known about the misconduct and they failed to stop it.⁴¹ In this case, the Individual Defendants made the decisions to break the law; they controlled the unfair and deceptive conduct; and they personally collected many millions of dollars from the deception.

- 217. Each individual defendant knowingly and intentionally sent sales representatives to promote opioids to prescribers in Arizona thousands of times.
- Each individual defendant knew and intended that the sales reps in Arizona would unfairly and deceptively promote opioid sales that are risky for patients, including by:
 - falsely blaming the dangers of opioids on patients instead of the addictive drugs;
 - pushing opioids for elderly patients, without disclosing the higher risks;
 - pushing opioids for patients who had never taken them before, without disclosing the higher risks;
 - pushing opioids as substitutes for safer medications, with improper comparative
 - falsely assuring prescribers and patients that reformulated OxyContin was safe;
 - pushing prescribers and patients to use higher doses of opioids, without disclosing the higher risks;
 - pushing prescribers and patients to use opioids for longer periods of time, without disclosing the higher risks; and
 - pushing opioid prescriptions by doctors that Purdue knew were writing dangerous prescriptions.
- Each individual defendant knew and intended that the sales representatives would not tell prescribers and patients in Arizona and Pinal County the truth about Purdue's opioids. Indeed, they knew and intended these unfair and deceptive tactics to achieve their purpose by concealing the truth.
- 220. Each individual defendant knew and intended that prescribers, pharmacists, and patients in Arizona would rely on Purdue's deceptive sales campaign to prescribe, dispense, and take Purdue opioids. Securing that reliance was the purpose of the sales campaign.

⁴¹ See A.R.S. § 10-830.

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- 221. Each individual defendant knew and intended that staff reporting to them would pay top prescribers tens of thousands of dollars to encourage other doctors to write dangerous prescriptions across the State of Arizona as well as in Pinal County.
- 222. Each individual defendant knew and intended that staff reporting to them would reinforce these misleading acts through thousands of additional acts in Pinal County including by sending deceptive publications to Plaintiff's local prescribers and deceptively promoting Purdue opioids at Plaintiff's local healthcare facilities and other institutions.
- Each individual defendant knew and intended that staff reporting to them would reinforce these misleading acts through thousands of additional acts in Arizona, including by sending deceptive publications to Arizona prescribers and deceptively promoting Purdue's opioids in Pinal County.
- Each individual defendant knowingly and intentionally took money from 224. Purdue's deceptive business in Arizona.
- Each individual defendant knowingly and intentionally sought to conceal his or 225. her misconduct.
 - 1. Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler
- 226. The opioid epidemic can be largely traced back to eight people in a single family—the Sacklers—who made decisions for their own pecuniary benefit that caused much of the opioid epidemic. The Sackler family owns Purdue, and have always held a majority of the seats on its Board. They controlled their own privately held drug company, and as a result, the Sacklers had the power to decide how their addictive narcotics were sold. They hired hundreds of workers to carry out their plan, and they fired those who failed to sell enough drugs. They got more patients on opioids, at higher doses, and for longer, than ever before. And to reward themselves, they paid themselves billions of dollars. They should be held accountable now.

2. The Sacklers' Misconduct Leading To The 2007 Judgment

227. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was neither new, nor accidental. Indeed, it was particularly unfair, deceptive, unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they presided over a decade of illegal and immoral conduct, which led to criminal convictions, a judgment of this Court, and commitments that Purdue would not deceive doctors and patients again. That background confirms that their subsequent and sustained misconduct was knowing and intentional.

228. Purdue Frederick Company, the Sacklers' first drug company, was purchased by them in 1952. In 1990, they created Purdue Pharma Inc. and Purdue Pharma L.P. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler took seats on the Board. For events before July 2012, this Complaint uses "the Sacklers" to refer to them. David Sackler joined the Board in July 2012. From that time forward, "the Sacklers" includes him as well.

229. The Sacklers insisted that the family control Purdue at all times. From 1990 until today, the family has consistently held the majority of seats on the Board. In 1994, Jonathan Sackler issued a memorandum to Purdue staff requiring that the Sacklers should receive "all Quarterly Reports and any other reports directed to the Board."

230. Purdue launched OxyContin in 1996. It quickly earned the superlative "honor" of becoming one of the deadliest drugs of all time. One scientist, Curtis Wright, who evaluated OxyContin wrote in his original review, admonished Purdue that "Care should be taken to limit competitive promotion."⁴³ The Sacklers disagreed.

231. The Sacklers were—and have always been—behind Purdue's decision to

⁴² Purdue Pharma Inc.'s 1991 filings with the Secretary of State of Connecticut state that it was incorporated in New York on October 2, 1990. Richard, Ilene, Jonathan, and Kathe Sackler are all listed as directors on the earliest (1991) report. Beverly, Mortimer, and Theresa all appear on the 1995 report. (*See* Office of Secretary of State Denise W. Merill, https://www.concord-sots.ct.gov/CONCORD/online?sn=PublicInquiry&eid=9740.)

⁴³ Curtis Wright ultimately secured OxyContin's approval for widespread use. Shortly afterward, Curtis Wright left his government position and joined Purdue within two years of his departure.

deceive doctors and patients about the risks and benefits of Purdue's opioids. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined that doctors had the beneficial but crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often, even as a substitute for Tylenol. The truth was that OxyContin is more potent than morphine. Richard directed Purdue staff not to tell doctors the truth, because the truth would reduce OxyContin sales.

232. In 1999, Richard Sackler became the President of Purdue. Jonathan, Kathe, and Mortimer were Vice Presidents. The company hired hundreds of sales representatives and taught them all the false claims they would need to sell drugs. Purdue managers tested the sales representatives on the most important false statements during training at company headquarters. In February of 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state. Meanwhile, Richard Sackler came up with Purdue's grand plan for the onslaught of negative publicity for his massive money-maker: blame and stigmatize people who become addicted to opioids. Sackler wrote, "We have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."

233. The Sacklers delighted in their success by landing on the front page of the *New York Times* which reported that "OxyContin's sales have hit \$1 billion, more than even Viagra's." The only dark spot? The article reported that "OxyContin has been a factor in the deaths of at least 120 people, and medical examiners are still counting."⁴⁴

234. When *Time* magazine published an article about OxyContin deaths, Purdue employees told Richard Sackler they were worried. Richard responded with his thematic message to the staff: *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue. "We intend to stay the course and speak out for people in pain—who far outnumber the drug addicts abusing our product."

⁴⁴ Meier, Barry, *Sales of Painkiller Grew Rapidly, But Success Brought a High Cost* (Mar. 5, 2001) https://www.nytimes.com/2001/03/05/business/sales-of-painkiller-grew-rapidly-but-success-brought-a-high-cost.html.

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235. Meanwhile, Purdue kept pushing opioids and people kept dying. Soon, the company was engulfed in a wave of investigations by state attorneys general and regulators. In 2003, Richard Sackler left his position as President of Purdue. After a few more years of investigation, Jonathan, Kathe, and Mortimer Sackler resigned from their positions as Vice Presidents. But those resignations were superficial. The Sacklers remained in control of the company and continued to direct Purdue's deceptive marketing campaign.

- By 2006, prosecutors found damning evidence that Purdue intentionally deceived doctors and patients about its opioids. In May 2007, The Purdue Frederick Company confessed to a felony and effectively went out of business. However, the Sacklers continued their opioid business in two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.
- The Sacklers voted to admit in an Agreed Statement of Facts that, for more than 237. six years, supervisors and employees *intentionally* used to deceive doctors about OxyContin: "Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."45
- The Sacklers entered into a plea agreement that stated: "Purdue is pleading 238. guilty as described above because Purdue is in fact guilty."46 Those intentional violations of the law happened while Richard Sackler was President; Jonathan, Kathe, and Mortimer were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all on the Board. The Sacklers also voted for Purdue to enter a Corporate Integrity Agreement with the U.S. government. The agreement required the Sacklers to ensure that Purdue did not deceive doctors and patients again. As part of the agreement, the family promised to comply with rules that prohibit deception about Purdue opioids. They were required to complete hours of training to ensure that they understood the rules. They were

⁴⁵ See, e.g., Attachment B to Plea Agreement in United States v. The Purdue Frederick Co., Inc., Case No. 1:07-cr-00029-JPJ: Purdue Agreed Statement of Facts, ("PASF") at ¶ 20.

^{46 2007-05-09} Plea Agreement. https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-

- 239. Finally, the Sacklers voted to enter into a Consent Judgment ("2007 Judgment"). The 2007 Judgment ordered that Purdue "shall not make any written or oral claim that is false, misleading, or deceptive" in the promotion or marketing of OxyContin. The judgment further required that Purdue provide balance regarding risks and benefits in all promotion of OxyContin. That judgment required balance in presentation of the risks of taking higher doses for longer periods and the risks of addiction, overdose, and death.⁴⁸
- 240. The 2007 Judgment also required that Purdue establish and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities:

"Upon identification of potential abuse or diversion," Purdue must conduct an inquiry and take appropriate action, "which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." 49

241. The 2007 Judgment and related agreements should have ended the Sacklers' misconduct for good. Instead, the Sacklers decided to expand their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

3. The Sacklers Continue Their Misconduct from The 2007 Judgment

242. From the 2007 Judgment to 2018, the Sackler family controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times than they otherwise could. They insisted

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⁴⁹ *Id*.

guilty-plea-5-10-2007.pdf.

⁴⁷ 2007-05-09 Plea Agreement. https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf.

⁴⁸ 2007-05-15 Consent Judgment, *Commonwealth v. Purdue Pharma L.P. et al.*, No. 07-1967(B), Mass. Super. Ct.

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that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied and adopted unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. The family was well informed: They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise representatives face-to-face.

- The Sacklers' iron rule impacted everyone in the company from the top down. When they berated sales managers, the managers turned around and passed angry messages to the sales representatives in the field. When Richard Sackler complained to sales managers, sales managers threatened their sales representatives with termination.
- In July 2007, staff informed the Sacklers that more than 5,000 cases of "adverse events" had been reported to Purdue in just the first three months of 2007. Staff also told the Sacklers that Purdue received 572 "Reports of Concern" about abuse and diversion of Purdue opioids during Q2 2007. Shockingly, staff reported to the Sacklers that they completed only 21 field inquiries in response to these reports. Staff also told the Sacklers that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to regulators or law enforcement authorities.
- Purdue's intentional failure to report abuse and diversion continued unabated, even though the 2007 Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even directing sales representatives to stop visiting them, the Sacklers chose to keep pushing opioids to whoever prescribed the most.
- The Sacklers were further aware that Purdue staff members continued to mail 246. out thousands of deceptive marketing materials. The single most-distributed material was

COUNSELORS AT LAW

volume #1 of Purdue's "Focused and Customized Education Topic Selections in Pain Management" ("FACETS"). In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life." In the same material, Purdue also falsely told doctors and patients that signs of addiction are actually "pseudoaddiction," and that doctors should respond by prescribing more opioids. Staff told the Sacklers that another of the publications they had sent most often to doctors was "Complexities in Caring for People in Pain." In it, Purdue again reiterated the false claim that warning signs of addiction are really "pseudoaddiction" that should be treated in the worst way possible: with more opioids.

- 247. At the same time, Purdue was making more money than expected. A few months earlier, there had been a projected a profit of \$407,000,000; now it expected more than \$600,000,000. The Sacklers had every reason to know that Purdue employed 301 sales representatives to promote opioids and that sales representatives were the largest group of Purdue employees by far. In comparison, Purdue employed only 34 people in drug discovery.
- 248. As a result of Purdue's overwhelming number of sales representatives—which varied from a low of 300 reps in mid-2007 to a peak of over 700 representatives in 2015—the impact of Purdue on Arizona and Pinal County was significant and direct—from the 2007 felony conviction to 2018, Purdue sales representatives visited Plaintiff's local prescribers regularly.
- 249. In August of 2007, Howard Udell was serving as Purdue's top lawyer, even after his 2007 criminal conviction for assisting Purdue in misleading doctors and patients by claiming that OxyContin was less prone to abuse than similar drugs. He warned the Sacklers about the negative press OxyContin was receiving.
- 250. In October of 2007, the Sacklers learned that Purdue received 284 Reports of Concern about abuse and diversion of Purdue's opioids in Q3 2007, and they conducted only 46 field inquiries in response. Moreover, they received 39 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities.
 - 251. By late 2007, Purdue expected to collect more than half its total revenue from

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sales of 80mg OxyContin—its most powerful, most profitable, and most addictive pill.

- 252. In January 2008, the Sacklers had every reason to know that Purdue still employed 304 sales representatives and they were succeeding at the goal of promoting higher doses of opioids. Purdue's net sales were just over \$1 billion in 2007, almost double what the company had projected. OxyContin accounted for more than 90% of those sales.
- 253. Purdue received 689 Reports of Concern about abuse and diversion of Purdue's opioids in Q4 2007, and they conducted only 21 field inquiries in response. Purdue received 83 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities. The Sacklers did nothing to comply with their obligations.
- 254. Instead of complying with their legal obligations, the Sacklers wanted more details on tactics for pushing sales, including the distribution and use of savings cards for Purdue opioids.
- 255. The Sacklers made it a point to become personally involved in various decision-making process of the company, ranging from selling opioids door-to-door and arranging inperson visits to doctor's offices and hospitals, to pressuring Purdue's sales forces to increase orders—whatever the cost.
- 256. The Sacklers also ensured that their top-performing sales representatives were rewarded. For example, top sales representatives were rewarded with bonuses and lavish, all-expense-paid vacations to tropical islands, hoping all the while that Purdue's relatively less productive sales representatives would hone in on the perks of increasing their sales, and ignore the clear risks of pushing higher doses of Purdue's opioids on vulnerable patients.
- 257. By 2008, Purdue was working on a crush-proof reformulation of OxyContin to extend Purdue's patent monopoly. The Sacklers learned that another company was planning clinical research to test whether crush-proof opioids were actually safer for patients. The Sacklers decided not to do the research because they wanted the profits from a new product.
- 258. In March of 2008, Richard Sackler focused on Purdue's strategy for selling more OxyContin. In response to clear indications that Purdue's VP of Sales, Russell Gasdia, had doubts about the company's increasingly aggressive sales tactics, Richard Sackler

COUNSELORS AT LAW

immediately ramped up the pressure, both pushing staff to sell more of the highest doses of opioids and get more pills in each prescription, as well as seeking to identify tactics for exceeding prior sales numbers. Under Sackler's direction, Purdue began preparing plans for how adding sales representatives, opioid savings cards, and promoting more intermediate doses of OxyContin could help increase sales.

- 259. Staff told these Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007.
- 260. In April of 2008, staff told the Sacklers that Purdue employed 304 sales representatives and that the representatives had obtained data showing which pharmacies stocked higher strengths of OxyContin, which helped them convince area doctors to prescribe the highest doses. At that time, the Sacklers learned that Purdue received 853 Reports of Concern about abuse and diversion of Purdue opioids in Q1 2008, and they had conducted only 17 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.
- 261. On April 18, 2008, Richard Sackler felt it important to install a CEO who would be loyal to the family. He recommended John Stewart the position because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.
- 262. When the Sacklers directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in Arizona. Purdue and the Sacklers tracked revenue and staff reported to the Sacklers that prescriptions of Purdue's highest doses provided seven-figure revenues per year and represented a significant percentage of Purdue's overall revenues from high-dose opioids.
- 263. In May of 2008, the Sacklers received more ideas from Purdue staff about ways to promote Purdue's opioids. One strategy that particularly pleased the Sacklers was to deflect blame from Purdue's addictive drugs by stigmatizing people who become addicted. "KEY

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MESSAGES THAT WORK" included this dangerous lie: "It's not addiction, it's abuse. It's about personal responsibility." This blame-the-victim, not-the-culprit approach has characterized the Sacklers' response to the opioid crisis they helped create.

Meanwhile, Richard Sackler pushed Purdue's opioid savings cards. 67,951 264. patients had used Purdue's opioid savings cards, and that the cards provided a discount on a patient's first five prescriptions. Predictably, after five prescriptions, many patients would face significant withdrawal symptoms if they tried to stop taking opioids. 27% of patients (more than 18,000 people) had used the cards for all five prescriptions.

In July of 2008, Purdue's Fleet Department reported to the Sacklers that Purdue had bought one hundred new Pontiac Vibes for the expanded sales force. Staff also told the Sacklers that Purdue received 890 Reports of Concern regarding abuse and diversion of Purdue's opioids in Q2 2008 and had conducted only 25 field inquiries in response. Staff reported to the Sacklers that they received 93 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.

266. Staff also told the Sacklers that they promoted Purdue's opioids in various presentations, which echoed the company's messaging from presentations such as "The Assessment and Management of Chronic Pain with an Emphasis on the Appropriate Use of Opioid Analgesics" and "The Role of Urine Drug and other Biofluid Assays in Pain Through these presentations, the Sacklers intentionally ensured that a Management." dangerous (and false) message would be disseminated to Arizona doctors and elsewhere—i.e., Purdue's opioids were the best way to manage chronic pain and that urine tests protected patients from addiction were both part of Purdue's unfair and deceptive scheme.

In October of 2008, surveillance data monitored by Purdue indicated a "wide 267. geographic dispersion" of abuse and diversion of OxyContin "throughout the United States." The Sacklers learned that "availability of the product" and "prescribing practices" were key factors driving abuse and diversion of OxyContin. On the same day, Purdue had begun a new "Toppers Club sales contest" for sales representatives to win bonuses, based on how much a representative increased OxyContin use in her territory and how much the representative

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increased the broader prescribing of opioids—the same "availability of product" and "prescribing practices" factors that worsen the risk of diversion and abuse. Purdue also knew it received 163 tips to Purdue's compliance hotline during Q3 2008, but did not report any of them to the authorities.

- 268. To the contrary, the Sacklers' decided to expand Purdue's sales forces, which effectively increased both the number of in-person visits to Arizona prescribers, as well as the disastrous consequences that would follow.
- 269. The Sacklers wanted to hire a new staff member who would contact prescribers electronically and would promote Purdue opioids through the deceptive website Partners Against Pain.
- Purdue received 122 tips to Purdue's compliance hotline during the first quarter of 2009, one of which was from an outside monitor. The Sacklers did nothing to stop the compliance problems, including the improper use of OxyContin marketing materials and opioid savings cards.
- 271. In addition to disregarding non-compliance, the Sacklers further instructed Purdue management to disregard supervision requirements under federal law mandating that—in order to mitigate the high risk of misconduct by sales representatives—Purdue managers needed to supervise sales representatives in-person at least five days each year.⁵⁰
- 272. Still, the Sacklers and Purdue created new sales territories and expanded sales staff. The expansion was focused on the most prolific opioid prescribers, because "there are a significant number of the top prescribers" that Purdue had not been able to visit with its smaller force of sales reps.
- By July of 2009, Purdue employed 429 sales reps. Richard Sackler was not satisfied with that number, wanting more.
- By August of 2009, the 80mg OxyContin pill was far-and-away Purdue's best performing drug. Purdue sold many more kilograms of active ingredient in the 80mg dose

Purdue Corporate Integrity Agreement section III.K., p. 23-24 (May 8, 2007), http://www.pharmacomplianceforum.org/docs/resources/PurdueCIA.pdf.

than any other dose (about 1,000 kilograms: literally a ton of oxycodone).

275. Purdue and the Sacklers reviewed their newest OxyContin sales campaign, with the slogan: *Options*. The *Options* campaign exemplified the strategy that Purdue would follow for years to come—pushing doctors and patients up the ladder to higher doses. To make it easy for sales representatives to promote higher doses, suggesting that doctors could or should adjust the patient's dose as frequently as every one-to-two days. They planned to advertise the *Options* campaign in medical journals reaching 245,000 doctors.

276. By 2009, more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the result reported to the Sacklers the summer before. Purdue and the Sacklers also decided to advertise OxyContin using a special television network and that thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.

277. As set forth throughout this Complaint, the Sackler Defendants paved the way for the opioid epidemic in Pinal County by organizing and ensuring the execution of an intentional, underhanded strategy to combine strong-arm sales tactics with misrepresentation about the benefits and risks of Purdue's opioids, and to debase and defame Purdue's victims. The Sacklers accomplished their goal through not only their individual and combined actions, but also through the actions of their executive-agents, including Peter Boer, Judith Lewent, Cecil Pickett, Paulo Costa, Ralph Snyderman, John Stewart, Russel Gasdia, Mark Timney and Craig Landau. And they did so while making themselves extraordinarily wealthy. Ultimately, a single family, the Sacklers, drove much of the opioid epidemic, at the expense of Pinal, Arizona, as well as the entire nation.

J. John Kapoor and Michael Babich Led Insys's Misconduct

278. John Kapoor ("Kapoor"), the founder and majority owner of Insys, and Michael Babich ("Babich"), the former CEO and President of Insys, led a nationwide conspiracy to profit using bribes and fraud to cause the illegal distribution of Subsys.

279. Kapoor and Babich conspired to bribe practitioners in various states, including in Arizona, many of whom operated pain clinics, in order to get them to prescribe Subsys. In

exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, many of whom were not diagnosed with cancer, and therefore did not need Subsys.

- 280. Kapoor and Babich also conspired to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when it was prescribed for non-cancer patients. They achieved this goal by setting up a "reimbursement unit" which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers.
- 281. Kapoor and Babich fueled the opioid epidemic by paying doctors to needlessly prescribe Subsys for patients who did not need it, and without complying with Arizona law, thus putting patients at risk and contributing to the current opioid crisis. Kapoor and Babich committed fraud, placing profit before patient safety, to sell a highly potent and addictive opioid.

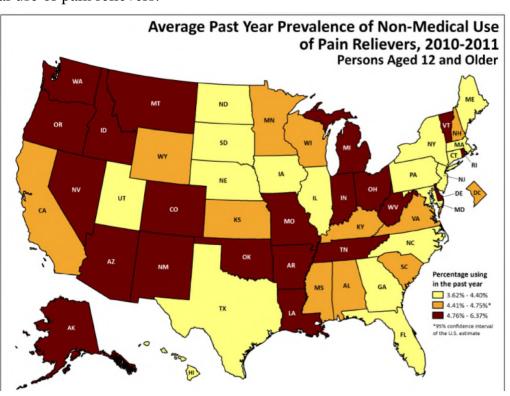
K. Distributor Defendants' Violation of Duty

- 282. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.
- 283. Specifically, under A.R.S. § 36-2523(A), all "[p]ersons registered to manufacture, distribute or dispense controlled substances"—*i.e.*, "Registrants"—are obligated to design and operate a system to disclose to the registrant suspicious orders of controlled substances, especially opioids. Each of the Distributor Defendants is a registrant for purposes of this section and, therefore, must satisfy certain reporting requirements of any and all "suspicious orders." Orders of controlled substances that are either unusual in size or frequency, or otherwise substantially deviate from a normal pattern, qualify as "suspicious orders."

L. Distributor Defendants Knew or Should Have Known they Were Facilitating Widespread Opioid Diversion

284. Opioid diversion in the supply chain has always been a widespread problem and has been highly publicized. Numerous publications, studies and other materials promulgated by Arizona agencies and regulators as well as professional health organizations have highlighted the epidemic rate of opioid abuse and overdose rates in Pinal County, as well as throughout the United States.

285. Prescription drug abuse is one of the fastest-growing drug problems in the United States, particularly in Arizona. In 2010-2011, 4/76%-6.37% of Arizonans engaged in non-medical use of pain relievers.



286. To combat the problem of opioid diversion, regulators provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions.

287. Since 2006, regulators have conducted one-on-one briefings with distributors regarding downstream customer sales, their due diligence responsibilities, and their legal and

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regulatory responsibilities (including the responsibility to know their customers and report suspicious orders). The distributors were provided with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were also given case studies, legal findings against other registrants, and profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. These materials pointed out "red flags" distributors should look for in order to identify potential diversion, to help distributors understand their duties with respect to diversion control.

Since 2007, regulators have hosted conferences to provide distributors with 288. updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major distributors, including AmerisourceBergen and Cardinal Health attended at least one of these conferences. The conferences allowed the distributors to ask questions, raise concerns, and request clarification on policies and procedures intended to prevent opioid diversion.

Since 2008, regulators have participated in numerous meetings and events with the legacy Healthcare Distribution Management Association ("HDMA"), now known as the Healthcare Distribution Alliance ("HDA"), an industry trade association for wholesalers and distributors. Regulatory representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.⁵¹ (HDMA, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," (2008).

290. On September 27, 2006 and again on December 27, 2007, regulators sent letters to all relevant opioid distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due

⁵¹ See, e.g., HDA.org, Issues in Distribution, Prescription Drug Abuse and Diversion (2018) (describing various resources "address[ing] the industry's approach to countering diversion and ensuring the safe supply of medicines to licensed entities across the supply chain"),

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diligence on controlled substance customers as part of a program to maintain effective controls against diversion. These letters reminded these distributors that they were required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. These letters explained that as part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of all orders prior to filling.

- In late-2007, regulators sent a follow-up letter to all relevant opioid distributors, providing guidance and reinforcing the legal requirements outlined in the correspondence referenced in above. This letter reminded these distributors that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised these distributors that they must perform an independent analysis of a suspicious order prior to the sale to determine if controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.
- 292. The Distributor Defendants were also on notice that their own industry group, the HDMA, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" that stressed the critical role of each member of the supply chain in distributing controlled substances.
- 293. Opioid distributors themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.
- 294. For example, a Cardinal executive recently claimed that it uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."
 - 295. These assurances, in addition to obligations imposed by law, show that

https://www.hda.org/issues/prescription-drug-abuse-and-diversion.

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Distributor Defendants understand and have undertaken a duty to protect the public against diversion from their supply chains, and to curb the opioid epidemic.

296. However, despite these statements and duties, Distributor Defendants have knowingly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties recovered regulators.

297. In 2008, Cardinal Health paid a \$34 million penalty to settle allegations about opioid diversion taking place at several of its warehouses. Again in 2012, Cardinal reached an administrative settlement to resolve allegations of opioid diversion between 2009 and 2012 in multiple states. Even more recently, in December 2016, Cardinal settled similar allegations of opioid diversion, paying \$34 million plus penalties. During the investigation of Cardinal, evidence was discovered that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy that was suspected of opioid diversion. Cardinal took no action, failed to report these suspicious transactions, and did not cut off the supply of drugs to the pharmacy. Instead, Cardinal's opioid shipments to the pharmacy increased to almost 2 million doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

298. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against the diversion of particular controlled substances into non-medically necessary channels. It has been reported that AmerisourceBergen has been subpoenaed for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

- 299. Although these Distributor Defendants have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry which generates billions of dollars in revenue.
 - 300. Plaintiff does not bring causes of action based on violations of federal statutes

and regulations. However, the existence of these complicated regulatory schemes shows Defendants' intimate knowledge of the dangers of diversion of prescription opioids and the existence of a thriving illicit market for these drugs. The Distributor Defendants breached their duties to Plaintiff despite this knowledge and longstanding regulatory guidance of how to deter and prevent diversion of prescription opioids.

M. The Pharmacy-Distributor Defendants Knew or Should Have Known They Were Facilitating Widespread Opioid Diversion

301. Pharmacy Distributor Defendants Walgreen Arizona Drug Co.; Walmart Inc. f/k/a Wal-Mart Stores, Inc. d/b/a Wal-Mart Pharmacy Warehouse # 32 and Wal-Mart Pharmacy Warehouse # 45; and Smith's Food and Drug Centers Inc. d/b/a Fry's Pharmacies and Fry's Food and Drug Stores earned enormous profits by flooding the State of Arizona, including Pinal County, with prescription opioids. They gained unique knowledge of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Rather than act to stem the flow of opioids into communities like Pinal County, the Pharmacy-Distributor Defendants participated in and profited from the oversupply.

302. The Pharmacy-Distributor Defendants have publicly acknowledged the risks of opioids and assured the public that public health and safety are their highest priorities. However, their public representations belied their own wrongdoing that contributed to the opioid epidemic. The Pharmacy-Distributor Defendants have recklessly or negligently permitted opioid diversion to occur, engaging in a consistent pattern of illegally distributing prescription opioids, while failing to uphold their duty to report such suspicious orders.

303. For instance, in 2016, Walgreens issued a press release captioned "Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths." However, on information and belief,

⁵² Press Release, Walgreens, Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths (Feb. 9, 2016), <a href="http://news.walgreens.com/press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press-releases/general-news/walgreens-leads-fight-against-press

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Walgreens, the second-largest pharmacy store chain in the United States, has been penalized for serious and flagrant violations regarding its distribution of opioids.

304. Similarly, in 2017, Walmart acknowledged the need for a "solution to the [opioid] epidemic" and noted the epidemic has "devastated so many families and communities across America." However, on information and belief, Walmart has also paid settlements to resolve allegations of violations in connection with Walmart's distribution of opioids to various states, including Texas.

N. The Pharmacy Defendants Understood But Violated Their Duties

305. Pharmacy Defendants Bashas' Inc. d/b/a Bashas' United Drug; Smith's Food & Drug Centers Inc. d/b/a Fry's Pharmacies and Fry's Food and Drug Stores; American Drug Stores Inc. d/b/a Osco Drug, Inc. a/k/a Osco Drug #968; Safeway Inc.; Sun Life Family Health Center; Vaden Corp.; Walgreen Arizona Drug Co. d/b/a Walgreens Pharmacy # 01076, Walgreens Pharmacy # 06129, Walgreens Pharmacy # 02963, Walgreens Pharmacy # 04188, Walgreens Pharmacy # 06333, Walgreens Pharmacy # 06440, Walgreens Pharmacy # 09264, Walgreens Pharmacy # 09460, Walgreens Pharmacy # 09652, Walgreens Pharmacy # 10505 and Walgreens Pharmacy # 10998; Walmart, Inc. f/k/a Wal-Mart Stores, Inc. d/b/a Wal-Mart Pharmacies a/k/a Wal-Mart Pharmacy 10-1218, Wal-Mart Pharmacy 10-1381, Wal-Mart Pharmacy 10-2778, Wal-Mart Pharmacy 10-3751 and Wal-Mart Pharmacy 10-4430; and d/b/a/ Costco Pharmacy # 436, Costco Pharmacy # 481, and Costco Pharmacy # 1028, earned enormous profits by flooding the State of Arizona, including Pinal County, with prescription opioids. They gained unique knowledge of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Rather than act to stem the flow of opioids into communities like Pinal County, they participated in and profited from the oversupply. Further, on information and belief, each

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 $[\]frac{prescription-drug-abuse-with-new-programs-to-help-curb-misuse-of-medications-and-the-rise-in-overdose-deaths.htm.}{}$

⁵³ Press Release, Walmart, Walmart Supports the State of Emergency Declaration on Opioids (Oct. 26, 2017), https://news.walmart.com/2017/10/26/walmart-supports-state-of-emergency-declaration-on-opioids.

of the Pharmacy Defendants has committed and continues to commit serious and flagrant violations of their duties under Arizona law regarding—*inter alia*—recordkeeping and dispensing opioids to Pinal County patients.

O. The Prescriber Defendants Facilitated Defendants' Scheme

Defendants") represent an important component of the Manufacturer Defendants' scheme to flood the State of Arizona, including Pinal County, with a wildly unnecessary amount of opioids. In return for the Manufacturer Defendants' bribes, kickbacks and/or all- expenses-paid "speaking engagements," and/or significant revenues to their respective businesses, the Prescriber Defendants facilitated the Manufacturer Defendants' scheme by (i) passing out "savings cards" to encourage patients who had never tried opioids before ("opioid naïve" patients) to buy the Manufacturer Defendants' drugs; (ii) increasing these patients' respective dosages without regard for the risk that the patients would become addicted; and/or (iii) prescribing, dispensing, selling, possessing and/or maintaining opioids in in violation of applicable Arizona laws and Arizona regulations.

307. Prescriber Defendant Harinder K. Takyar is a formerly licensed Medical Doctor who for years treated and prescribed opioids to Pinal County patients. On information and belief, Defendant Takyar is known for prescribing unreasonably high dosages of opioids to Pinal County patients without a legitimate medical purpose, and has been investigated as an overprescriber of opioids; for example, in October of 2017, Defendant Takyar's authority to prescribe opioids was revoked, on the grounds that he "routinely prescribed large quantities of oxycodone," in violation of the applicable standard of care. Prior to surrendering his license to practice medicine in 2018, Defendant Takyar maintained an office in the Town of Florence, Arizona, which is located in Pinal County. As reported on OpenPaymentsData.CMS.gov, Defendant Takyar has received undisputed payments from opioid manufacturers. Among other violations of Arizona laws and prevailing medical standards applicable to Pinal County clinicians and patients, Defendant Takyar facilitated the Defendants' scheme by (1) violating restrictions on his authority to prescribe opioids pursuant to his Consent Agreement for

Practice Restriction with the Arizona State Board of Medicine; (2) deviating from the standard of care by prescribing opioids to patients whose medical and clinical histories demonstrated unreasonably high risks of opioid diversion and/or abuse; (3) administering opioids to patients without conducting necessary physical exams; (4) falsely documenting that medically necessary exams were performed prior to administering opioids to his patients, even though no such exams took place; (5) failing to substantiate and justify the opioids he prescribed to patients; and (6) placing his patients at risk of opioid-related overdose or otherwise creating an addictive state or contributing to a pre-existing addictive state by failing to monitor patients' opioid prescribing, failing to access the Arizona Controlled Substance Monitoring Program prior to such prescribing, and failing to conduct urine screens to mitigate the serious risks of opioid-related harm to which Defendant Takyar exposed his patients by prescribing opioids inappropriately.

P. Each of the Defendant's Misconduct Has Injured and Continues to Injure Pinal County and Its Citizens

308. In addition to the significant social costs associated with illicit drug use, Defendants' predatory and willful misrepresentations in manufacturing, marketing and/or distributing opioids have imposed enormous tax-based economic damages on Pinal County, including tax revenue expended incident to providing various public services that Pinal County is required to provide to its citizens under Arizona law, including healthcare- and crime-related costs. These revenues would not have been expended but for the opioid crisis that Defendants willfully and foreseeably caused in Arizona generally and Pinal County specifically.

309. As Defendants' opioids continue to wreak havoc on Pinal County's community and incapacitate and/or kill Pinal County's citizens, Pinal County has also been deprived of the benefits these citizens would have conferred to Pinal County's community but for Defendants' wrongful conduct. Pinal County has lost both the productivity of Pinal County's citizens who have been hospitalized, incarcerated, killed, or otherwise incapacitated by Defendants' dangerous products, including the property and/or sales taxes these citizens

would have paid had Defendants' simply told the truth about the risks and benefits of opioids.

1. Tax Revenue Expended—Healthcare-Related Costs

- 310. Drugs kill more Arizonans each year than motor vehicle accidents.⁵⁴ Indeed, the number of drug-related deaths in Arizona is among the highest in the nation and continues to increase each year.
- 311. While Defendants reaped billions of dollars in profits from their deceptive conduct, Pinal County suffered—and continues to suffer—irreparable damage in the form of increased healthcare-related costs, which Arizona law requires that Pinal County pay to protect the health and safety of its citizenry. Pinal County would not have incurred these costs had Defendants not concealed the true dangers (and misrepresented the true benefits) of the relevant opioids. In particular, each of the Defendants has directly and proximately caused Pinal County to divert precious tax dollars and local resources from the County's coffers, in order to address its citizens' increasing need for county-funded, opioid-related health services, including: (a) specialty services—e.g., skilled nursing care, substance abuse treatment, pain management clinics, etc.; (b) emergency medical treatment for the Pinal County jail population; and (c) family services and other social programs. As the opioid epidemic that Defendants created and/or failed to abate in Pinal County has raged, Plaintiff has paid and continues to pay the significant, increasing costs of providing these important public services to patients suffering from opioid addiction, opioid withdrawal, and other opioid-related conditions.
- 312. Pursuant to A.R.S. § 36-2913, the County also makes financial contributions to provide Arizona Health Care Cost Containment System ("AHCCCS") enrollees in Pinal County with the healthcare items and services they need. Pinal participates in several AHCCCS programs. Enrollment in these programs is limited to particularly vulnerable populations—such as elderly and low-income persons, as well as individuals suffering from

Executive Office of the President of the United States, *Arizona Drug Control Update - 2010*, p. 1 (2010), https://obamawhitehouse.archives.gov/sites/default/files/docs/state_profile-arizona.pdf.

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certain disabilities or other serious medical conditions.⁵⁵ Plaintiff's contributions to AHCCCS cover a wide variety of healthcare services, including specialty services such as hospital and skilled nursing care as well as substance abuse treatment and pain management.

313. Moreover, as a direct and proximate result of the Defendants' misdeeds as described in this Complaint, Plaintiff has been forced to make increasingly large expenditures to the Pinal County Health Department. including for health services, vital records, immunizations, family counseling and drug testing, as well as other programs provided to families that have been and continue to be negatively impacted by the opioid epidemic that Defendants created, precipitated and/or failed to abate in Pinal County.

(a) Specialty Treatment Admissions—Skilled Nursing Care, **Substance Abuse Treatment, Pain Management Clinics**

A substantial portion of the County's allocations to AHCCCS go to skilled 314. nursing facility ("SNF") care. SNFs provide long-term care for vulnerable patients who require nursing care institution services because they cannot live independently. Since late-April of 2018, the Arizona Opioid Epidemic Act ("AOEA") has both generally required that Arizona prescribers limit initial prescriptions for opioids to no more than a five-day supply, and generally prohibited these providers from issuing prescriptions for more than 90 morphine milligram equivalents ("MMEs").⁵⁶ However, these general provisions do <u>not</u> apply to patients receiving SNF care; hence, SNF patients in Pinal County who have never received an opioid prescription—i.e., "Opioid Naïve" patients—remain uniquely vulnerable to adverse, opioid-related incidents.⁵⁷

In addition, since 2010, the County has made significant expenditures to provide the people of Pinal County with medically necessary substance abuse treatment.

See A.R.S. §§ 36-2901(6).

⁵⁶ See A.R.S. §§ 32-3248(A), (B)(6)

See id.; see also Arizona State Board of Pharmacy, Frequently Asked Questions: 2018 **Epidemic Opioid** 1-2 (Apr. 18, 2018), Arizona Act, https://pharmacypmp.az.gov/sites/default/files/Opioid%20Epidemic%20Act%20FAQ 041820 18.pdf.

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316. Pinal County's specialty treatment-related expenditures also involve pain management services. Pursuant to A.A.C. R9-10-1021, "[a] medical director of an outpatient treatment center that is authorized to provide pain management services shall ensure that . . . [these] services are provided under the direction of . . . [a] physician, or . . . [a] nurse practitioner licensed . . . with advanced pain management certification from a nationally recognized accreditation or certification entity."58 Where pain management services involve opioids, Arizona law further requires that the "medical practitioner discuss[] the risks and benefits of using a controlled substance with a patient," as well as document the discussion in the patient's medical record, along with the patient's history of substance abuse disorder, the nature and intensity of the patient's pain and the objectives used to determine whether the patient is being successfully treated."⁵⁹ As a direct and proximate result of the Defendants' misconduct, Pinal County has allocated—and continues to allocate—enormous portions of its general and special revenues to finance AHCCCS and Health Department services, to meet the medical needs of the people of Pinal County.

Treatment—Opioid-Related **(b) Emergency** Medical **Emergencies**

317. The number of opioid-related encounters in Arizona hospitals increased from 20,365 in 2009 to 51,473 in 2016—an increase of roughly 153%. 60 Opioids have a significant impact upon Arizona's medical care system due to the volume of encounters involving opioids, and the costs of these encounters. While the full economic burden of opioids upon the healthcare system is difficult to precisely calculate, a reasonable measure may be derived using hospital reported charges adjusted using national cost to charges ratios. Using this approach, the cost of all 'opioid-related' encounters in Arizona from 2009-2015 increased by

A.A.C. R9-10-1021.1.

See A.A.C. R-10-1021.3.

Arizona Department of Health Services, 2016 Arizona Opioid Report, p. 5-6 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelinesrecommendations/prescribing-guidelines/arizona-opioid-report.pdf.

125% and—in 2016—equaled $\$341,457.011.^{61}$ The average cost per opioid-related unique encounter is $\$8,241.^{62}$

- 318. As utilization of county-funded, opioid-related emergency medical services ("EMS") has increased in Pinal County, the County has made—and continues to make—enormous contributions to provide its jail populations with these life-saving services.
- 319. On information and belief, the incidence of opioid-related hospitalizations in Pinal County—which can be tracked by various medical billing and documentation codes, such as the Healthcare Common Procedure Coding System ("HCPCS") and the American Medical Association's Current Procedural Terminology (CPT), including National Drug Codes (NDCs) and International Classification of Diseases ("ICD") codes—similarly increased during the relevant period.
- 320. As the number of opioid-related hospital encounters in Pinal County has ballooned, the costs of treatment and supplies have also increased. This increase has strained—and continues to strain—Plaintiff's coffers, which provide the financial resources needed to respond appropriately to an increasingly large demand for opioid-related emergency medical services among Pinal County's jail population.
- 321. For example, Pinal County dedicates substantial tax revenues to finance the provision of healthcare services to the inmate populations of various correctional facilities within the County. The County contracts with third-party providers, such as Wexford Correctional Health, to provide these health services to inmates of Pinal County Adult Detention Center, Pinal County Youth Justice Center and other correctional facilities within the County. Healthcare providers such as Wexford Correctional Health ("Wexford") use the County's funding to provide various opioid-related services to these inmates, including—but not limited to—the administration of opioid antagonists (*e.g.*, Naloxone, Narcan) to inmates suffering from opioid-related conditions. For example, inmates often arrive to Plaintiff's jails

⁶¹ Arizona Department of Health Services, *2016 Arizona Opioid Report*, p. 5 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf.

in opioid-related respiratory distress, requiring Wexford's nursing staff to administer Naloxone or other opioid antagonists to these inmates to save their lives. These nurses report that the opioid crisis has increased the liability and work load for nurses, detention officers and other correctional staff, as these patients/inmates require closer observation and increased time from both medical and detention staff in providing care. Moreover, inmates often experience severe withdrawal and require hospitalization for management.

- 322. Moreover, Plaintiff's correctional staff also report that these problems are frequently present with new intakes to Plaintiff's jails, who swallow drugs prior to their arrest or during the arrest process in order to bring opiates or other illegal drugs into the facility. These new inmates often share these drugs with other inmates, putting them at risk for overdose or death and requiring additional resources from the County to mitigate this risk. Plaintiff's correctional staff often see the same inmates return repeatedly throughout the year as they commit crimes to support their addiction. These correctional staff members have also noted an increase in the number of inmates who admit to using opioids, with fentanyl numbers especially increasing within the past year. Plaintiff has learned that these inmates' addictions started with the use of legally prescribed narcotics, with inmates turning to street drugs when they can no longer fill their opioid prescriptions. In large part, these inmates decide to buy illicit opioids because they are much easier to obtain and often cheaper than prescription opioids, particularly for individuals who live in the relatively more rural areas of Pinal where public transportation is sparse.
- 323. At the same time, the costs of providing emergency medical services in opioid emergencies have likewise increased, making the administration of opioid antagonists, such as Narcan and Naloxone, more expensive.

(c) Family Services And Other Social Programs

324. Defendants' actions that fueled the opioid crisis have also devastated many American families, and the child welfare system has felt the effects. Between 2010 and 2012,

Id., *supra*, n. 216 at p. 6.

after more than a decade of sustained declines in the national foster care caseload, the number of children entering foster care started to rise—just as opioid deaths began to spike.⁶³ Today, more than 258,000 children are in the foster care system nationwide, nearly 18,000 of which are right here in Arizona.⁶⁴ Plaintiff dedicates substantial portions of its tax revenues to help support the health and safety of these vulnerable populations by funding opioid-related public services and programs for families and children, including opioid-related ancillary services.

325. Arizona's foster-care system is designed to protect children from abuse and neglect, removing children from their homes if they face an "unreasonable risk of harm." The Arizona Department of Child Safety ("ADCS") defines "unreasonable risk of harm" to mean that "the totality of the circumstances specific to the incident, the behavior and/or action or inaction of the parent, guardian or custodian placed the child at a level of risk of harm to which a reasonable (ordinarily cautious) parent, guardian or custodian would not have subjected the child." ADCS has characterized the increase in opioid-related cases in emergency departments as "alarming," and the Arizona Substance Abuse Partnership ("ASAP") has likewise recognized the importance of removing a child living in home in which opioid abuse is occurring.

326. The number of Arizona children that are removed from their homes by the state foster care system—*i.e.*, the "Removal Rate"—is about three-times higher than the national

⁶³ Laura Radel, Substance Use, the Opioid Epidemic, and the Child Welfare System: Key Findings from a Mixed Methods Study, p. 2 (Mar. 7, 2018), https://aspe.hhs.gov/system/files/pdf/258836/SubstanceUseChildWelfareOverview.pdf.

Mary Jo Pitzl, 'Biggest challenge, biggest opportunity': DCS aims to keep more kids at home, THE ARIZONA REPUBLIC (Feb. 4, 2018), https://www.azcentral.com/story/news/local/arizona-investigations/2018/02/04/child-welfare-agency-policy-aims-clearly-define-when-safe-leave-kids-home/881208001/.

⁶⁵ Bob Ortega, *A Horrifying Journey through Arizona foster care*, and why we don't know how many more children may be abused, THE ARIZONA REPUBLIC (Jun. 4, 2017), https://www.azcentral.com/story/news/local/arizona-investigations/2017/06/04/arizona-foster-care-child-abuse/362836001/.

⁶⁶ Department of Economic Security—Division of Children Youth and Families, *Child and Family Services: Annual Progress Report 2012, State of Arizona*, p. 225 (Jun., 2012), https://dcs.az.gov/file/5405/download?token=1ZRcWAmV.

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average.⁶⁷ Moreover, from 2013 to 2016, the Removal Rate increased by roughly 30 percent⁶⁸—well outside the normal range, even for states hit hardest by the opioid epidemic,⁶⁹ and after factoring in Arizona's high childhood poverty rate. 70 As a result, the state-financed Arizona child welfare agencies and their community partners that provide foster care payments and certain foster care services struggle to meet families' needs—with many counties experiencing at least a 50% increase in their respective caseloads and local agencies reporting family members across multiple generations are more frequently becoming addicted to, or dying from, opioids.⁷¹ To help protect the health and safety of affected families and children in the County who both have been negatively impacted by the above-referenced trends in Arizona's foster care system and are in need of opioid-related services that are not accessible through state welfare agencies or their community partners, Pinal County has spent and continues to spend its own tax revenues to support these families with county-funded services and other programs, including opioid-related ancillary services.

Moreover, the costs to the County associated with providing these services and 327. programs have increased over the arc of the opioid epidemic, as evidenced by government data. In March of 2018, for instance, regulators confirmed that "the high levels of opioid sales

⁶⁷ B. Ortega, Arizona's DCS: Why are kids taken away? Too often the answer is unknown, **REPUBLIC** THE **ARIZONA** (Mar. 2017), 14. https://www.azcentral.com/story/news/local/arizona-investigations/2017/01/22/arizonadepartment-child-safety-why-kids-taken-away-too-often-answer-unknown/96539080/; see also L. Radel, supra, Note 69 at p. 8 ("Child welfare caseloads nationally increased by 10 percent between fiscal years 2012 and 2016.")

Nicole Carrol, Arizona child welfare: There are some issues we just won't let go, THE ARIZONA REPUBLIC (Aug. 28, 2016), https://www.azcentral.com/story/news/local/arizonainvestigations/2016/08/28/arizona-child-welfare-there-some-issues-we-just-wont-letgo/89313770/.

⁶⁹ E. Birnbaum, Opioid crisis sending thousands of children into foster care, THE HILL (Jun. 20, 2018), https://thehill.com/policy/healthcare/393129-opioid-crisis-sending-thousands-ofchildren-into-foster-care.

⁷⁰ Emily Bregel, Despite state progress in Arizona, 'a lot of desperation, isolation', ARIZONA DAILY STAR (Mar. 9, 2018), https://tucson.com/news/local/despite-state-progress-in-arizonaa-lot-of-desperation-isolation/article fb7af064-224b-11e8-a96b-fbbdaba17d9c.html.

⁷¹ See L. Radel, supra, Note 69 at p. 4.

and drug overdose deaths spreading across the nation in recent years raise the concern that additional counties may experience increased child welfare caseloads in the coming years."

These regulators reported that, while drug-related hospitalization rates vary widely between substances such as opioids, stimulants and hallucinogens, the opposite is true with respect to foster care, such that "a 10 percent increase in hospitalizations due to any of these substance types corresponded with approximately a 2 percent increase in foster care entry rates."

On information and belief, as the rate of foster care entries has increased in the County as a result of the opioid epidemic, the demand for county-funded family services, ancillary service and other public assistance from the County has also increased for these vulnerable individuals.

328. To address that demand, Plaintiff has provided—and continues to provide—a variety of services and programs that are vitally important to abating the opioid epidemic in Pinal County that resulted from Defendants' misconduct as described in this Complaint.. For example, staff members of Plaintiff's correctional facilities acknowledge the increased need for such services and programs and emphasize that these services and programs are a critical component of abating the opioid epidemic in the County. These staff members report that many of the inmates in Pinal County who have been or currently are incarcerated for opioid-related crime come from addicted families, in which opioid abuse is both ubiquitous and considered "normal." To rehabilitate these individuals and mitigate the risk of opioid-related recidivism, the County has paid and continues to pay significant portions of its tax revenues in connection with providing these inmates with various ancillary services and other forms of county-funded public assistance geared toward reversing the physiological and psychological damage that opioid addiction has had on these inmates and their families.

329. Because Plaintiff allocates its own funds to provide ancillary and other public services to protect the health and safety of Pinal's citizenry who are suffering from opioid-related family crises, and because these services would not have been required or would have been required to a lesser degree absent the Defendants' misconduct, Pinal County has

⁷² See L. Radel, supra, Note 69 at p. 8-9.

⁷³ See L. Radel, *supra*, Note 69 at p. 4-5.

accordingly been damaged by the impact of Defendants' misconduct in the form of increased expenditures for family services and other social programs, such as those referenced above.

(d) County Tax Expenditures For Public Health Department Services

- 330. Plaintiff currently finances the Pinal County Public Health District (the "District") through a local health tax. Revenues from the County's health tax help fund any array of services—including opioid-related services—performed by the District for the benefit of Plaintiff's citizenry, including, *inter alia*, immunizations and other community health services as well as data analytics and reporting.
- 331. As a direct, proximate result of the Defendants' misdeeds as described in this Complaint, the County's allocations to the District—which, *inter alia*, protects the health and safety of Plaintiff's citizenry by providing and arranging for health and social services, including opioid-related services—have increased significantly over the arc of the opioid epidemic in Pinal County.

2. Tax Revenue Expended—Crime-Related Costs

- 332. In addition to imposing on Plaintiff significantly higher healthcare-related costs, Defendants' scheme has spread thin Plaintiff's resources by causing a sharp uptick in criminal justice costs, including those associated with opioid-related arrests, investigations and other local police and court programs. The funds necessary to maintain the day-to-day operating expenses and equipment for these programs come from Plaintiff's revenues from Plaintiff's local taxes. Indeed, while the health-related damages that the Defendants' foreseeably caused to the County are sizable, the County's opioid-related tax expenditures in the criminal justice context are staggering.
- 333. For example, the County made significant allocations to the following law enforcement efforts as a direct and proximate result of Defendants' misconduct described in this Complaint: (a) the sheriff, (b) drug investigations and diversion (c) intensive supervision, (d) probation, (e) criminal justice attorneys, (f) jail services, and (g) court costs.

(a) Pinal County Sheriff's Office

334. While the County has expended significant funds to abate the opioid epidemic through increased investment in Pinal County Sheriff's Office ("PCSO"), the epidemic—ignited and continually fueled by Defendants' ongoing misconduct—remains a constant threat to the health and safety of Pinal's citizens. To date, the PCSO has lawfully seized and disposed of nearly 300 lbs. of prescription medication, including opioids. Absent Defendants' misconduct as described in this Complaint, the County's expenditures associated with financing the PCSO's aforementioned efforts would not have been incurred by the County or would have been significantly smaller.

(b) Drug, Gang & Violent Crime Investigations

335. Pinal County has dedicated and continues to dedicate significant resources to identify, investigate, arrest, and prosecute criminals who facilitate drug diversion in the County. Plaintiff has suffered and continues to suffer sizeable expenditures in an effort to mitigate opioid diversion in the County. Absent Defendants' misconduct as described in this Complaint, these expenditures would not have been incurred by the County or would have been significantly smaller.

(c) Supervision and Probation

336. The County also expends substantial funds to finance supervision and probation for adults and juveniles over the last several years. Thousands of these individuals were or are under supervision and/or on probation because of drug-related crimes, including opioid-related crimes. Indeed, since 2009, Pinal has conducted thousands of opioid drug tests on adult probationees, a significant portion of whom tested positive for opioids. Absent Defendants' misconduct as described in this Complaint, Plaintiff's expenditures associated with these probationees would not have been incurred by the County or would have been significantly smaller.

(d) Criminal Justice Attorneys

337. In abating the public nuisance that the Defendants created and/or exacerbated in Pinal County—which remains ongoing—the County has incurred significant costs on the County's criminal justice attorneys, including prosecutors and public defenders. From 2017-

2018, for example, the Pinal County Attorney's Office ("PCAO") prosecuted over 500 cases involving opioids. Absent Defendants' misconduct as described in this Complaint, these expenditures would not have been incurred by the County or would have been significantly smaller.

(e) Jail Services

338. The County's efforts to abate the ongoing public nuisance that the Defendants created and/or exacerbated in Pinal County have also led to significant increases in jail services costs. Plaintiff's correctional officers report that the opioid crisis has increased the liability and world load for correctional staff, including detention officers and other security personnel. Inmates suffering from opioid addiction and other opioid-related health conditions require closer observation and increased security to prevent opioid diversion, which is particularly common among newly arriving inmates, who swallow opioids (*e.g.*, fentanyl) before or during the arrest process in order to smuggle these opioids into Plaintiff's jails and share them with other inmates, placing these inmates at risk of overdose and death. Absent Defendants' misconduct as described in this Complaint, the County's expenditures associated with opioid-related jail services would not have been incurred by the County or would have been significantly smaller.

(f) Court Costs

339. As the Defendants' misconduct has continually frustrated the County's efforts to protect the health and safety of its citizens, the County has allocated and continues to allocate substantial sums to finance the operation of courts. Absent Defendants' misconduct as described in this Complaint, these expenditures would not have been incurred by the County or would have been significantly smaller.

340. Further, the County's contributions to community punishment programs for drug offenders have increased in recent years. Absent Defendants' misconduct as described in this Complaint, these expenditures would not have been incurred by the County or would have been significantly smaller.

(g) Arrests and Investigations to Protect Public Health and

Safety

341. The effects of Defendants' deceptive marketing and distribution scheme has further impacted Plaintiff by creating various public nuisances—including public health and safety hazards—which Plaintiff is obligated to abate. Plaintiff has dedicated substantial tax dollars to maintain the public safety of places, such as county parks, schools and public lands, where patients-turned-addicts attempt to congregate. Plaintiff has also dedicated significant funds to enable the Pinal County Sheriff's Office ("PCSO") to mitigate the increase in drug and property crimes committed by opioid addicts who are both actively looking to feed their addictions, as well as suffering from serious medical conditions associated with the spread opioid abuse, including—*inter alia*—Hepatitis B and C, HIV, sexually transmitted diseases and methicillin-resistant staphylococcus aureus ("MRSA").

- 342. From 2000 to 2018, there were many recorded opioid overdose cases in Pinal County, each of which required the dedicated time of several law enforcement officers to perform various tasks, including—but not limited to—investigations, arrests, bookings, report writing, evidence impounding, scene security and follow up time. During the same time period, Pinal County law enforcement agencies made many arrests for drug-related charges, including for possession and/or sale of opioids and opioid-related paraphernalia.
- 343. In abating the opioid nuisance to protect the health and safety of citizens of Pinal County, Plaintiff has suffered pecuniary damages, proximately caused by Defendants' misrepresentations and omissions of material fact.

3. Tax Revenue Forgone

- 344. Tax revenue forgone is a consequence of incapacitation. The principal events associated with incapacitation include specialty treatment, hospitalization, incarceration and death. As a result of such incapacitation, the citizens of Pinal County who became addicted to Defendants' opioids are unable to work or contribute to Pinal County's financial health through sales, property and other taxes.
- 345. The Pinal County Health Department (the "Department") reports hundreds of overdoses in Pinal County. Roughly 11% of those overdoses were fatal. Whether or not the

overdose was fatal, roughly one-third of these overdoses involved the administration of Naloxone to treat opioid-related respiratory distress. Most of these overdoses occurred among adults aged 25-44 years. Moreover, over a dozen infants have been born in Pinal County suffering from neonatal abstinence syndrome ("NAS").

(a) Specialty Treatment—SNFs, Substance Abuse Treatment, Pain Management Treatment, etc.

- 346. As a direct consequence of the Defendants' misconduct as described in this Complaint, the number of individuals who became addicted to the Manufacturer Defendants' drugs increased. Once addicted, these individuals draw on Plaintiff's public services without contributing to Plaintiff's community. These individuals have become incapacitated by their addictions and, instead of working, struggle to function and resist relapse.
- 347. The lost tax revenue attributable to these patients is especially significant for Plaintiff, as the vast majority of such patients would—but for their addiction—be productive members of Plaintiff's community.

(b) Hospitalization

- 348. Patients who are hospitalized in connection with opioid-related emergencies are likewise unable to contribute to Pinal County's financial health with their labor or through the payment of taxes. Indeed, in 2018 the Arizona Department of Public Health reported that 97% of patients suffering from an opioid-related emergency survived the immediate pre-hospital event. Moreover, government estimates indicate that opioid-related hospital stays are consistently longer than those attributable to both hallucinogens and stimulants, including cocaine and methamphetamine. Longer hospital stays are usually more expensive and lead to larger losses of productivity for the hospitalized patient.
 - 349. Even if patients survive the immediate pre-hospital event and are successfully

AHCCCS—Division of Health Care Management, *Annual Report on Substance Abuse Treatment Programs: State Fiscal Year 2016*, p. 1, 3 (Dec. 31, 2016), https://www.azahcccs.gov/shared/Downloads/Reporting/AHCCCSDrugAbuseTreatmentProgramsReport_36-2023.pdf.

⁷⁵ See L. Radel, supra, Note 69 at p. 4.

stabilized at, and discharged from, the treating hospital, these patients are frequently referred to specialty treatment facilities in Pinal County and continue to be incapacitated by their addictions.

(c) Death

350. According to government estimates, some 50,000 Americans died from an opioid overdose in 2016—*i.e.*, 137 people per day, and roughly one person every 12 minutes. The emotional devastation caused by Defendants' despicable actions is impossible to quantify; however, as described above, the purely economic consequences of the opioid epidemic can and have been successfully tracked in terms of lives, lost productivity, healthcare, criminal justice and other costs. Accordingly, in 2017 President Donald Trump's Council of Economic Advisers estimated that the economic consequences to the nation of the opioid drug epidemic cost the United States \$504 billion in 2015 alone, prompting the President to declare the opioid crisis a nationwide public health emergency.

351. Plaintiff has been hit even harder by the opioid crisis. In the past decade, 5,932 Arizonans died from opioid-induced causes. Many Pinal County individuals died in recent years from opioid-related causes, who would not have died but for the Defendants' misconduct as described in this Complaint.

WAIVER OF CERTAIN CLAIMS FOR RELIEF

352. Pinal County expressly disclaims and waives any and all right to recovery, whether financial, injunctive, or equitable, relating to or arising out of the distribution by any person of any product, or the provision of any service, pursuant to any exclusive contracts with the federal government, including—but not limited to—McKesson Corporation's ("McKesson") Pharmaceutical Prime Vendor Contract ("PPV Contract") with the United States Department of Veteran Affairs and other, similarly exclusive distribution contracts between any Defendants and any federal government agencies or other federal entities. Specifically, Pinal County expressly disclaims and waives any and all right to recover against

⁷⁶ Money.com, *Here's What I Would Cost to Fix the Opioid Crisis, According to 5 Experts* (Nov. 27, 2017), http://money.com/money/5032445/cost-fix-opioid-crisis/.

any of the Distributor or Pharmacy Distributor Defendants under the terms and conditions of any PPV Contract or any similar contract.

- 353. Pinal County further commits that it will not, in any forum, rely on or raise the PPV Contract or any similar contract in connection with its allegations and/or prosecution in this matter.
- 354. Pinal County agrees that should Defendants present evidence sufficient for the trier of fact to determine that Pinal County's injuries were caused, in whole or in part, by the distribution of products or provision of services through the PPV or similarly exclusive contracts with federal government agencies or entities, Defendants are entitled to a reduction of their liability proportionately by the extent to which the trier of fact determines that any injury to Pinal County was caused by goods or products distributed and/or services provided through the PPV or any similar contract.

V. <u>CAUSES OF ACTION</u>

FIRST CAUSE OF ACTION

PUBLIC NUISANCE

Violations of Arizona Revised Statutes § 13-2917

(Against All Defendants)

- 355. Plaintiff re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 356. A.R.S. § 13-2917(A)(1) provides that "[i]t is a public nuisance" for anything "[t]o be injurious to health, indecent, offensive to the senses or an obstruction to the free use of property that interferes with the comfortable enjoyment of life or property by an entire community or neighborhood or by a considerable number of persons."
- 357. A.R.S. § 13-2917(A) notes that a public nuisance is "no less a nuisance because the extent of the annoyance or damage inflicted is unequal."
- 358. Plaintiff brings this action under A.R.S. § 13-2917(C) to abate, enjoin, and prevent the public nuisance created by the Defendants.

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- 359. Each Defendant, acting individually and in concert, has created or assisted in the creation of a condition that is injurious to the health and interferes with the comfortable enjoyment of life and property of entire communities or neighborhoods or of any considerable number of persons in Pinal County in violation of A.R.S. § 13-2917.
- 360. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic described above in the County, and that harm outweighs any offsetting benefit.
- 361. Defendants knew or should have known that their promotion, distribution, and prescribing of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance—i.e., the opioid epidemic.
- 362. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain, sabotaging these practitioners' ability to protect their patients from opioid-related injuries and conditions. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.
- 363. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.
- Pursuant to A.R.S. § 13-2917(C), the County requests an order providing for abatement of the public nuisance that Defendants created or assisted in the creation of, and enjoining Defendants from future violations A.R.S. § 13-2917.
- 365. Additionally, as a direct and proximate cause of the public nuisance that Defendants' created, the County has suffered and will continue to suffer harm, and is entitled to damages in an amount to be determined at trial.

SECOND CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

- 366. Pinal County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 367. Under Arizona law, a cause of action arises for negligence when a defendant owes a duty to a plaintiff and breaches that duty, and proximately causes the resulting injury.
- 368. Each Defendant owed a duty of care to Pinal County, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.
- 369. In violation of this duty, Defendants failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids by misrepresenting the risks and benefits associated with opioids and by distributing and prescribing dangerous quantities of opioids.
- 370. As set forth, the Manufacturer Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid doses without added risk, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life without posing significant additional risks. Each of these misrepresentations made by Defendants violated the duty of care to Pinal County.
- 371. The Distributor Defendants knew of the serious problem posed by prescription opioid diversion and were under a legal obligation to take reasonable steps to prevent diversion.
- 372. The Distributor Defendants negligently distributed suspiciously large quantities of potent opioids and failed to report such distributions. As such, the Distributor Defendants violated their duty of care by moving these dangerous products into Pinal County in such quantities, facilitating misuse and abuse of opioids.

	373.	Plaintiff	is	not	asserting	a	cause	of	action	under	the	federal	Contr	olled
Subst	ances A	act or othe	r fe	deral	l controlled	l sı	ubstanc	es 1	aws, inc	cluding	—bu	ıt not lim	ited to-	—the
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374. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, Pinal County has suffered and will continue to suffer harm, and is entitled to damages in an amount to be determined at trial.

THIRD CAUSE OF ACTION

NEGLIGENCE PER SE

(Against All Defendants)

- 375. Pinal County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 376. Defendants' actions violate Arizona statutes designed to protect the public from harm. In particular, Defendants' actions violate A.R.S. § 36-2501 *et seq*. (the "AZCSA") and Arizona requirements regarding the dispensing of medication.
- 377. A.R.S. § 36-2523 requires all AZCSA registrants—which includes manufacturers and distributors—under the AZCSA to maintain records in accordance with Arizona's regulations on the dispensing of medication.
- 378. A.R.S. § 36-2524 states that certain controlled substances shall be distributed by an AZCSA registrant to another registrant only pursuant to an authorized order form.
- 379. A.R.S. § 36-2531(A)(3) prohibits and makes it unlawful for any person to intentionally or knowingly refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice, or information required under the AZCSA.
- 380. A.R.S. § 36-2531(A)(6) prohibits and makes it unlawful for any person to intentionally or knowingly sell, buy, exchange or give away any preparation subject to the AZCSA, unless the preparation is used for a legitimate medical purpose and in compliance with the AZCSA.
 - 381. A.R.S. § 36-2531(C)(1) prohibits and makes it unlawful for any person

intentionally or knowingly to distribute as a registrant certain controlled substances, except pursuant to an order form in accordance with the AZCSA.

- 382. A.R.S. § 36-2531(2) prohibits and makes it unlawful for any person intentionally or knowingly to furnish false or fraudulent material information in, or omit any material information from, any application, report or other document required to be kept or filed under the CSA or any record required to be kept by the AZCSA.
- 383. A.R.S. § 36-2531(E) states that a person shall not provide a false prescription for a controlled substance or knowingly or intentionally acquire or obtain possession of a controlled substance by means of forgery, fraud, deception or subterfuge, including the forgery or falsification of a prescription or the nondisclosure of a material fact.
- 384. A.R.S. Title 32, Chapter 18 governs the Arizona Board of Pharmacy and statutory requirements for dispensing medication.
- 385. A.R.S. § 32-1964(A) states that "[e]very proprietor, manager or pharmacist in charge of a pharmacy shall keep in the pharmacy a book or file in which that person places the original of every prescription order of drugs, devices or replacement soft contact lenses that compounded or dispensed at the pharmacy. This information shall be serially numbered, dated and filed in the order in which the drugs, devices or replacement soft contact lenses were compounded or dispensed. A prescription order shall be kept for at least seven years. The proprietor, manager or pharmacist shall produce this book or file in court or before any grand jury on lawful order. The book or file of original prescription orders is open for inspection at all times by the prescribing medical practitioner, the board and its agents and officers of the law in performance of their duties."
- 386. A.R.S. § 32-1983(B) provides that, "[a] full service wholesale permittee may furnish prescription-only drugs to a pharmacy or medical practitioner. The full service wholesale permittee must first verify that person holds a valid license or permit."
- 387. A.R.S. § 32-1983(C) provides that, "[t]he full service wholesale permittee must deliver prescription-only drugs to an authorized person or agent of that premises if: (1) [t]he full service wholesale permittee properly establishes the person's identity and authority; and

(2) [d]elivery to an authorized person or agent is used only to meet the immediate needs of a particular patient of the authorized person."

388. A.R.S. § 32-1983(D) provides that, "[a] full service wholesale permittee may furnish prescription-only drugs to a pharmacy receiving area if a pharmacist or authorized receiving personnel sign, at the time of delivery, a receipt showing the type and quantity of the prescription-only drug received. Any discrepancy between receipt and the type and quantity of the prescription-only drug actually received must be reported to the full service wholesale permittee by the next business day after the delivery to the pharmacy receiving area."

389. A.R.S. § 32-1983(E) provides that, "[a] full service wholesale permittee shall not accept payment for or allow the use of a person or entity's credit to establish an account for the purchase of prescription-only drugs from any other person other than the owner of record, the chief executive officer or the chief financial officer listed on the license or permit of a person or entity legally authorized to receive prescription-only drugs. Any account established for the purchase of prescription-only drugs must bear the name of the licensee or permittee."

390. Defendants' acts regarding the manufacture, distribution, and prescribing of opioids described in detail above violated each and every one of these Arizona laws. Defendants are liable for negligence *per se* in that the Defendants violated applicable Arizona laws, statutes, and regulations, in the manner in which they advertised, marketed, sold, and/or distributed opioid products. Plaintiff is a member of the class meant to be protected by the laws, statutes, and regulations which Defendants violated, and Plaintiff's injuries were caused by the violations. Further, Pinal County's citizens are within the class which these laws were designed to protect, and the harm to Plaintiff's citizens is of the nature the laws were designed to prevent. Consequently, Defendants' violations constitute negligent acts *per se* under Arizona law.

FOURTH CAUSE OF ACTION

UNJUST ENRICHMENT

(Against All Defendants)

- 391. Pinal County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 392. Each Defendant was required to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.
- 393. Rather than prevent or mitigate or wide proliferation of opioids into Pinal County, each Defendant instead chose to place its monetary interests first and each Defendant profited from prescription opioids sold in Pinal County.
- 394. Each Defendant also failed to maintain effective controls against the unintended and illegal use of the prescription opioids it or he manufactured, distributed, or prescribed, again choosing instead to place its or his monetary interests first.
- 395. Each Defendant therefore received a benefit from the sale, distribution, or prescription of prescription opioids to and in Pinal County, and these Defendants have been unjustly enriched at the expense of Pinal County.
- 396. As a result, Pinal County is entitled to damages on its unjust enrichment claim in an amount to be proven at trial.

FIFTH CAUSE OF ACTION

NEGLIGENT FAILURE TO WARN

(Against the Manufacturer Defendants)

- 397. Pinal County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 398. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable and ordinary care and skill and in accordance with applicable standards of conduct in adequately warning the medical profession about the risk of addiction from the use of

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opioid products, and not to over-promote and over-market opioid products so as to nullify, cancel out and render meaningless any written warnings about addiction, however inadequate, about the risk of addiction from the use of opioid products.

- 399. The Manufacturer Defendants breached their duty to exercise reasonable and ordinary care by affirmatively misleading and subsequently failing to warn the medical profession about the true risk of addiction from the use of opioid products. Moreover, the Manufacturer Defendants so over-promoted the products to nullify, cancel out and render meaningless any warnings in the labels about any addiction risk due to the Manufacturer Defendants' marketing, sales and promotional efforts that were designed to stimulate the use of opioid products in situations and for patients who should not have been using those drugs or should have used them only as a last resort before other means were used or other less addictive and dangerous drugs were prescribed.
- 400. As a direct and proximate cause of the Manufacturer Defendants' unreasonable and negligent conduct, Pinal County has suffered and will continue to suffer harm, and is entitled to damages in an amount to be determined at trial.

SIXTH CAUSE OF ACTION

FRAUDULENT TRANSFER

Violation of A.R.S. § 44-1004

(Against The Sackler Defendants)

- 401. Pinal County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 402. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling Pinal County to punitive damages
- 403. As set forth above, Pinal County possesses a variety of causes of action against Purdue and the other Defendants, and as soon as final judgment is entered in this action, Pinal County will possess a right to payment from Purdue.
 - 404. Pinal County has been harmed because Pinal County is informed and believes

that Purdue has been transferring assets to the Sacklers and other shareholders for years in order to avoid paying the judgment that will be owed Pinal County, as well as the multitude of other plaintiffs that have commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

- 405. Pinal County is informed and believes that Purdue transferred assets to the Sacklers and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors, including Pinal County.
- 406. Pinal County was harmed as a result of these transfers, and Pinal County is entitled to void them pursuant to Arizona Revised Statute § 44-1004.

SEVENTH CAUSE OF ACTION

CIVIL CONSPIRACY

(Against The Sackler Defendants)

- 407. Pinal County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 408. As alleged above, Purdue and the Sacklers engaged in a knowing and willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Individual Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection of its judgment against Purdue entered in this action.
- 409. After the Sacklers became aware in or about 1999 that Purdue faced potential liability because of the addictive nature of OxyContin, Purdue and the Sacklers conspired to shield the proceeds of their wrongdoing from creditors like Pinal County by stripping Purdue every year of hundreds of millions of dollars of profits from the sale of OxyContin and other opioid-containing medications via distributions from Purdue to shareholders, including the Sacklers and their extended family.
- 410. Purdue and the Sacklers, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in a coordinated, common course of conduct to commit acts of fraud.

411. P	Purdue and th	e Sacklers a	acted with	a common	understanding	or design to
commit unlawf	ful acts, as alle	eged herein, a	and acted p	ourposely, w	ithout a reasona	able or lawful
excuse, which	directly and p	roximately c	caused the	injuries alle	ged herein.	

- 412. Purdue and the Sacklers acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.
- 413. As a proximate result of Purdue and the Sacklers' conspiracy and the distributions of billions of dollars in profits to the Sacklers, Pinal County is informed and believes that Purdue lacks sufficient assets to satisfy its liabilities to Pinal County pursuant to the judgment entered in this action.
- 414. As a result of Purdue and the Sacklers' conspiracy, Pinal County is entitled to compensatory damages in an amount to be proved at trial.
- 415. As alleged herein, Purdue and the Sacklers' conspiracy was willful, malicious, oppressive, and fraudulent, entitling Pinal County to punitive damages.

EIGHTH CAUSE OF ACTION

Violations of the Arizona Consumer Fraud Act

A.R.S. § 44-1521 et seq.

(Against all Defendants)

- 416. Pinal County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 417. The Arizona Consumer Fraud Act is codified at A.R.S. § 44-1521 *et seq*. ("AZCFA"). The AZCFA establishes a comprehensive framework for redressing the violations of applicable law. The conduct at issue in this case falls within the scope of the AZCFA.
- 418. The AZCFA prohibits the "use or employment . . . of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression, or omission of any material fact with intent that others rely on such concealment, suppression, or omission, in connection with the sale or advertisement of any

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merchandise "Ariz. Rev. Stat. Ann. §44-1522. Defendants have engaged in and continue to engage in the same pattern of unfair methods of competition, and unfair and/or deceptive conduct pursuant to a common practice of misleading the public regarding the purported benefits and risks of opioids.

- But for these unfair method of competition and unfair and/or deceptive acts or practices in the conduct of trade or commerce, Pinal County would not have incurred the massive costs related to the epidemic caused by Defendants, as fully described above.
- Logic, common sense, justice, policy, and precedent indicate the Manufacturing Defendants' unfair and deceptive conduct has caused the damage and harm complained of herein. The Manufacturing Defendants knew or reasonably should have known that their statements regarding the risks and benefits of opioids were false and misleading, and that their statements were causing harm from their continued production and marketing of opioids. All Defendants knew or reasonably should have known that the proliferation of prescription opioids were causing damage to Pinal County. Thus, the harms caused by Defendants' unfair and deceptive conduct to Pinal County were reasonably foreseeable, including the financial and economic losses incurred by Pinal County.

VI. PRAYER FOR RELIEF

Pinal County prays that the Court issue:

- 1. An Order declaring that Defendants have created a public nuisance in violation of A.R.S. § 13-2917;
- 2. An Order enjoining Defendants from performing any further acts in violation of A.R.S. § 13-2917;
- 3. An Order mandating that Defendants abate the public nuisance that they created in the County in violation of A.R.S. § 13-2917;
 - 4. An Order that Defendants are negligent under Arizona law;
- 5. An Order that Defendants have been unjustly enriched at Pinal County's expense under Arizona law;
 - 6. An Order that Pinal County is entitled to recover all measure of damages

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permissible under the statutes identified herein	and under common l	aw, in an amount to be
proven at trial;		

- 7. An Order that judgment be entered against Defendants in favor of Pinal County;
- 8. An Order that Pinal County is entitled to attorney's fees and costs pursuant to any applicable provision of law;
 - 9. An Order voiding any fraudulent transfer by the Sacklers;
 - 10. Compensatory damages in a sum to be proven at trial;
 - 11. Punitive damages against Purdue and the Sacklers in a sum to be proven at trial;
- 12. An Order that the conduct alleged herein violates the Arizona Consumer Fraud Act;
- 13. An Order that Pinal County is entitled to damages pursuant to the Arizona Consumer Fraud Act;
- 14. An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts; and
- 15. An award of attorneys' fees and costs pursuant to the Arizona Consumer Fraud Act, *e.g.* A.R.S. § 44-1534.

VII. JURY TRIAL DEMAND

421. Pinal County demands a trial by jury on all claims and of all issues so triable.

DATED: September 25, 2019 FENNEMORE CRAIG, P.C.

/s/ J. Christopher Gooch

J. Christopher Gooch Scott Day Freeman Attorneys for Plaintiff Pinal County